UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

NITINOL MEDICAL TECHNOLOGIES, INC.
d/b/a NMT MEDICAL, INC.

Plaintiff,

v. Civil Action No. 04-12565-NG

AGA MEDICAL CORPORATION,

Defendants.

DECLARATION OF KATE SAXTON IN SUPPORT OF NMT MEDICAL, INC.'S OPPOSITION TO AGA MEDICAL CORPORATION'S MOTION TO DISMISS, OR IN THE ALTERNATIVE, TO TRANSFER

I, Kate Saxton, hereby declare that:

1. I am an associate at Wilmer Cutler Pickering Hale and Dorr LLP, counsel for Nitinol Medical Technologies, Inc. d/b/a/ NMT Medical, Inc. ("Plaintiff") in the above-captioned matter.

2. I submit this declaration in support of Plaintiff's Opposition to AGA Medical Corporation's Motion to Dismiss, or in the Alternative, to Transfer.

3. Attached hereto as Exhibit A is a true and correct copy of the Complaint in NMT Medical, Inc. v. AGA Medical Corporation, Civil Action No. 98-12506-NG (D. Mass.).

4. Attached hereto as Exhibit B is a true and correct copy of AGA Medical Corporation's Answer and Counterclaims in NMT Medical, Inc. v. AGA Medical Corporation, Civil Action No. 98-12506-NG (D. Mass.).

5. Attached hereto as Exhibit C is a true and correct copy of the Complaint in AGA Medical Corporation v. NMT Medical, Inc., Civil Action No. 04-4486 JMR/FLN (D. Minn.).

6. Attached hereto as Exhibit D is a true and correct copy of the docket report in NMT Medical, Inc. v. AGA Medical Corporation, Civil Action No. 98-12506-NG (D. Mass.).

7. Attached hereto as Exhibit E is a true and correct copy of the April 25, 2001 Order Regarding the Motion to Stay in NMT Medical, Inc. v. AGA Medical Corporation, Civil Action No. 98-12506-NG (D. Mass.).

8. Attached hereto as Exhibit F is a true and correct copy of a June 25, 2001 Receipt of Reexam Original Request in United States Patent and Trademark Office ("USPTO") file wrapper 90/006,043, "Aperture Occlusion Device."

9. Attached hereto as Exhibit G is a true and correct copy a February 5, 2003 Reexam Final Rejection in USPTO file wrapper 90/006,043, "Aperture Occlusion Device."

10. Attached hereto as Exhibit H is a true and correct copy an April 17, 2003 Notice of Appeal in USPTO file wrapper 90/006,043, "Aperture Occlusion Device."

11. Attached hereto as Exhibit I is a true and correct copy of the December 1, 2003 Order of Dismissal in NMT Medical, Inc. v. AGA Medical Corporation, Civil Action No. 98-12506-NG (D. Mass.).

12. Attached hereto as Exhibit J is a true and correct copy of an August 19, 2004 Board of Patent Appeals and Interferences decision reversing the Examiner's Decision in USPTO file wrapper 90/006,043, "Aperture Occlusion Device."

13. Attached hereto as Exhibit K is a true and correct copy of the September 7, 2004 NMT Medical, Inc. press release entitled "NMT Medical Announces Favorable Decision by U.S. Patent Office Board of Appeals."

14. Attached hereto as Exhibit L is a true and correct copy of a January 26, 2005 Notice of Intent to Issue A Reexam Certificate in USPTO file wrapper 90/006,043, "Aperture Occlusion Device."

15. Attached hereto as Exhibit M is a true and accurate copy of the Complaint in NMT Medical, Inc. v. AGA Medical Corporation, Civil Action No. 04-12565 (D. Mass.).

16. Attached hereto as Exhibit N is a true and accurate copy of the Summons and Return of Service in NMT Medical, Inc. v. AGA Medical Corporation, Civil Action No. 04-12565 (D. Mass.).

17. Attached hereto as Exhibit O is a true and accurate copy of the Summons and Return of Service in AGA Medical Corp. v. NMT Medical, Inc., Civil Action No. 04-4486 JMR/FLN (D. Minn.).

18. Attached hereto as Exhibit P is a true and accurate copy of NMT Medical Inc.'s Initial Disclosures Pursuant to Local Rule 26.2 and Fed. R. Civ. P. 26(a)(1) in NMT Medical, Inc. v. AGA Medical Corporation, Civil Action No. 98-12506 (D. Mass.).

19. Attached hereto as Exhibit Q is a true and accurate copy of AGA Medical Corporation's Initial Disclosures Pursuant to Local Rule 26.2 and Fed. R. Civ. P. 26(a)(1) in NMT Medical, Inc. v. AGA Medical Corporation, Civil Action No. 98-12506 (D. Mass.).

20. Attached hereto as Exhibit R is a true and accurate copy of www.amplatzer.com/cgi-bin/list/incl.cgi?setup_file=incl.usasetup.cgi&city=Boston&s…, printed March 9, 2005.

Signed this 28th day of March, 2005 under the pains and penalties of perjury.

/s/ Kate Saxton
Kate Saxton

EXHIBIT A

JS-44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

(a) PLAINTIFFS

Nitinol Medical Technologies, Inc.
and Lloyd A. Marks

DEFENDANTS

AGA Medical Corporation

(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF Suffolk
(EXCEPT IN U.S. PLAINTIFF CASES)

COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT _____
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

(c) ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER)
Hale and Dorr LLP
60 State Street
Boston, MA 02109

ATTORNEYS (IF KNOWN)

. BASIS OF JURISDICTION (PLACE AN "X" IN ONE BOX ONLY)

- 1 U.S. Government Plaintiff
- XX 3 Federal Question (U.S. Government Not a Party)
- 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (PLACE AN "X" IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

. ORIGIN (PLACE AN "X" IN ONE BOX ONLY)

1 Original Proceeding | ☐ 2 Removed from State Court | ☐ 3 Remanded from Appellate Court | ☐ 4 Reinstated or Reopened | ☐ 5 Transferred from another district (specify) | ☐ 6 Multidistrict Litigation | ☐ 7 Appeal to District Judge from Magistrate Judgment

NATURE OF SUIT (PLACE AN "X" IN ONE BOX ONLY)

CONTRACT
110 Insurance
120 Marine
130 Miller Act
140 Negotiable Instrument
150 Recovery of Overpayment & Enforcement of Judgment
151 Medicare Act
152 Recovery of Defaulted Student Loans (Excl. Veterans)
153 Recovery of Overpayment of Veteran's Benefits
160 Stockholders' Suits
190 Other Contract
195 Contract Product Liability

REAL PROPERTY
210 Land Condemnation
220 Foreclosure
230 Rent Lease & Ejectment
240 Torts to Land
245 Tort Product Liability
290 All Other Real Property

TORTS

PERSONAL INJURY
☐ 310 Airplane
☐ 315 Airplane Product Liability
☐ 320 Assault, Libel & Slander
☐ 330 Federal Employers' Liability
☐ 340 Marine
☐ 345 Marine Product Liability
☐ 350 Motor Vehicle
☐ 355 Motor Vehicle Product Liability
☐ 360 Other Personal Injury

PERSONAL INJURY
☐ 362 Personal Injury – Med. Malpractice
☐ 365 Personal Injury – Product Liability
☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
☐ 370 Other Fraud
☐ 371 Truth in Lending
☐ 380 Other Personal Property Damage
☐ 385 Property Damage Product Liability

CIVIL RIGHTS
☐ 441 Voting
☐ 442 Employment
☐ 443 Housing/ Accommodations
☐ 444 Welfare
☐ 440 Other Civil Rights

PRISONER PETITIONS
☐ 510 Motions to Vacate Sentence
HABEAS CORPUS:
☐ 530 General
☐ 535 Death Penalty
☐ 540 Mandamus & Other
☐ 550 Civil Rights
☐ 555 Prison Condition

FORFEITURE/PENALTY
☐ 610 Agriculture
☐ 620 Other Food & Drug
☐ 625 Drug Related Seizure of Property 21 USC 881
☐ 630 Liquor Laws
☐ 640 R.R. & Truck
☐ 650 Airline Regs.
☐ 660 Occupational Safety/Health
☐ 690 Other

LABOR
☐ 710 Fair Labor Standards Act
☐ 720 Labor/Mgmt. Relations
☐ 730 Labor/Mgmt. Reporting & Disclosure Act
☐ 740 Railway Labor Act
☐ 790 Other Labor Litigation
☐ 791 Empl. Ret. Inc. Security Act

BANKRUPTCY
☐ 422 Appeal 28 USC 158
☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
☐ 820 Copyrights
XX 830 Patent
☐ 840 Trademark

SOCIAL SECURITY
☐ 861 HIA (1395ff)
☐ 862 Black Lung (923)
☐ 863 DIWC/DIWW (405(g))
☐ 864 SSID Title XVI
☐ 865 RSI (405(g))

FEDERAL TAX SUITS
☐ 870 Taxes (U.S. Plaintiff or Defendant)
☐ 871 IRS – Third Party 26 USC 7609

OTHER STATUTES
☐ 400 State Reapportionment
☐ 410 Antitrust
☐ 430 Banks and Banking
☐ 450 Commerce/ICC Rates/etc.
☐ 460 Deportation
☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 810 Selective Service
☐ 850 Securities/Commodities/ Exchange
☐ 875 Customer Challenge 12 USC 3410
☐ 891 Agricultural Acts
☐ 892 Economic Stabilization Act
☐ 893 Environmental Matters
☐ 894 Energy Allocation Act
☐ 895 Freedom of Information Act
☐ 900 Appeal of Fee Determination Under Equal Access to Justice
☐ 950 Constitutionality of State Statutes
☐ 890 Other Statutory Actions

. CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE BRIEF STATEMENT OF CAUSE. DO NOT CITE JURISDICTIONAL STATUTES UNLESS DIVERSITY.)

Action for patent infringement under 35 U.S.C. Sec. 271

. REQUESTED IN COMPLAINT: CHECK IF THIS IS A CLASS ACTION ☐ UNDER F.R.C.P. 23

DEMAND $

CHECK YES only if demanded in complaint
JURY DEMAND: XX YES ☐ NO

I. RELATED CASE(S) IF ANY (See instructions): JUDGE _____ DOCKET NUMBER _____

TE 12/16/98

SIGNATURE OF ATTORNEY OF RECORD

I OFFICE USE ONLY

CEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

DISTRICT OF MASSACHUSETTS

1. TITLE OF CASE (NAME OF FIRST PARTY ON EACH SIDE ONLY) Nitinol Medical Technologies, Inc. v. AGA Medical Corporation

2. CATEGORY IN WHICH THE CASE BELONGS BASED UPON THE NUMBERED NATURE OF SUIT CODE LISTED ON THE CIVIL COVER SHEET. (SEE LOCAL RULE 40.1(A)(1)).

___	I.	160, 410, 470, R.23, REGARDLESS OF NATURE OF SUIT.	
XX	II.	195, 368, 400, 440, 441-444, 540, 550, 555, 625, 710, 720, 730, 740, 790, 791, 820*, 830*, 840*, 850, 890, 892-894, 895, 950.	*Also complete AO 120 or AO 121 for patent, trademark or copyright cases
___	III.	110, 120, 130, 140, 151, 190, 210, 230, 240, 245, 290, 310, 315, 320, 330, 340, 345, 350, 355, 360, 362, 365, 370, 371, 380, 385, 450, 891.	
___	IV.	220, 422, 423, 430, 460, 510, 530, 610, 620, 630, 640, 650, 660, 690, 810, 861-865, 870, 871, 875, 900.	
___	V.	150, 152, 153.	

3. TITLE AND NUMBER, IF ANY, OF RELATED CASES. (SEE LOCAL RULE 40.1(E)). None

4. HAS A PRIOR ACTION BETWEEN THE SAME PARTIES AND BASED ON THE SAME CLAIM EVER BEEN FILED IN THIS COURT? YES ☐ NO ☒

5. DOES THE COMPLAINT IN THIS CASE QUESTION THE CONSTITUTIONALITY OF AN ACT OF CONGRESS AFFECTING THE PUBLIC INTEREST? (SEE 28 USC 2403) YES ☐ NO ☒
IF SO, IS THE U.S.A. OR AN OFFICER, AGENT OR EMPLOYEE OF THE U.S. A PARTY? YES ☐ NO ☐

6. IS THIS CASE REQUIRED TO BE HEARD AND DETERMINED BY A DISTRICT COURT OF THREE JUDGES PURSUANT TO TITLE 28 USC 2284? YES ☐ NO ☒

7. DO ALL PARTIES IN THIS ACTION RESIDE IN THE CENTRAL SECTION OF THE DISTRICT OF MASSACHUSETTS (WORCESTER COUNTY) - (SEE LOCAL RULE 40.1(C)). YES ☐ NO ☒
OR IN THE WESTERN SECTION (BERKSHIRE, FRANKLIN, HAMPDEN OR HAMPSHIRE COUNTIES)? - (SEE LOCAL RULE 40.1(D)). YES ☐ NO ☒

8. DO ALL OF THE PARTIES RESIDING IN MASSACHUSETTS RESIDE IN THE CENTRAL AND/OR WESTERN SECTIONS OF THE DISTRICT? YES ☐ NO ☒
(a) IF YES, IN WHICH SECTION DOES THE PLAINTIFF RESIDE? _____

9. IN WHICH SECTION DO THE ONLY PARTIES RESIDING IN MASSACHUSETTS RESIDE? Eastern

10. IF ANY OF THE PARTIES ARE THE UNITED STATES, COMMONWEALTH OF MASSACHUSETTS, OR ANY GOVERNMENTAL AGENCY OF THE U.S.A. OR THE COMMONWEALTH, DO ALL OTHER PARTIES RESIDE IN THE CENTRAL SECTION? YES ☐ NO ☐ OR WESTERN SECTION: YES ☐ NO ☐

(PLEASE TYPE OR PRINT)

ATTORNEY'S NAME William F. Lee, Esq.
ADDRESS Hale and Dorr LLP 60 State Street Boston, MA 02109
TELEPHONE NO. (617) 526-6000

(Categorysheet - 3/97)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

NITINOL MEDICAL TECHNOLOGIES, Inc. and LLYOD A. MARKS,

Plaintiffs,

v.

AGA MEDICAL CORPORATION,

Defendant.

Civil Action No. _____

JURY TRIAL DEMANDED

98CV12506 NG

COMPLAINT FOR PATENT INFRINGEMENT

NATURE OF ACTION

This is an action under the patent laws of the United States, Title 35 of the United States Code, for infringement of United States Patent No. 5,108,420.

THE PARTIES

1. Plaintiff Nitinol Medical Technologies, Inc. ("Nitinol") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business in Boston, Massachusetts.

2. Plaintiff Lloyd A. Marks ("Marks") is a resident of Westfield, New Jersey.

3. Defendant AGA Medical Corporation ("AGA Medical"), is a Minnesota corporation, having its principal place of business in Golden Valley, Minnesota.

JURISDICTION AND VENUE

4. This is an action for patent infringement arising under Title 35 of the United States Code. Accordingly, this Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1338(a).

5. Venue is proper in this jurisdiction pursuant to 28 U.S.C. §§ 1391(b), 1391(c) and/or 1400(b).

ACTS GIVING RISE TO THE COMPLAINT

6. Plaintiff Marks is the inventor and owner by reassignment of United States Patent No. 5,108,420 (the "'420 patent"), entitled "Aperture Occlusion Device." A copy of the '420 patent is attached as Exhibit A.

7. Plaintiff Nitinol is the exclusive worldwide licensee of the right to make, use and sell products embodying the '420 patent and/or manufactured according to the methods of the '420 patent.

8. Defendant AGA Medical manufactures, offers for sale or sells medical devices which infringe one or more claim of the '420 patent.

9. Defendant AGA Medical is currently making, using or selling, and will, unless enjoined, continue to make, use or sell, medical devices infringing one or more claim of the '420 patent.

10. On information and belief, Defendant AGA Medical's acts of infringement are willful and deliberate.

WHEREFORE, plaintiffs Nitinol and Marks request that judgment be entered in their favor, and that they be granted the following relief:

i. A judgment that AGA Medical has infringed the '420 patent, and that such infringement has been willful;

ii. A permanent injunction restraining AGA Medical, its officers, agents, servants, employees and those acting in concert with it, from infringing the '420 patent;

iii. An award of damages sufficient to compensate Nitinol and Marks for the infringement complained of herein;

iv. An award of enhanced damages in the amount of three times the damages found or assessed, attorneys' fees, disbursements and costs of suit; and

v. Such other and further relief as the Court deems just and proper.

PLAINTIFFS HEREBY DEMAND TRIAL BY JURY.

Dated: December 10, 1998

NITINOL MEDICAL TECHNOLOGIES, INC. and LLOYD A. MARKS

By their attorneys,

William F. Lee (BBO #291960)
William G. McElwain (BBO #332510)
Dominic E. Massa (BBO #564694)
Hale and Dorr LLP
60 State Street
Boston, Massachusetts 02109
(617) 526-6000

US005108420A

United States Patent [19]

Marks

[11] Patent Number: 5,108,420

[45] Date of Patent: Apr. 28, 1992

[54] APERTURE OCCLUSION DEVICE

[75] Inventor: Lloyd A. Marks, Bryn Mawr, Pa.

[73] Assignee: Temple University, Philadelphia, Pa.

[21] Appl. No.: 649,593

[22] Filed: Feb. 1, 1991

[51] Int. Cl.[5] A61B 17/00

[52] U.S. Cl. 606/213; 606/78; 606/151; 606/157

[58] Field of Search 606/78, 151, 157, 158, 606/215, 108, 213; 128/898, 628, 686, 843, 831

[56] References Cited

U.S. PATENT DOCUMENTS

3,868,956	3/1975	Alfidi et al. .	
3,874,388	4/1975	King et al. .	
4,007,743	2/1977	Blake .	
4,170,990	10/1979	Baumgart et al. .	
4,425,908	1/1984	Simon .	
4,503,569	3/1985	Dotter .	
4,512,338	4/1985	Balko et al. .	
4,707,196	11/1987	Honma et al. .	
4,710,192	12/1987	Liotta et al. .	
4,744,364	5/1988	Kensey .	
4,758,222	7/1988	McCoy .	
4,805,618	2/1989	Ueda et al.	128/831
5,037,427	6/1991	Harada et al.	606/108

OTHER PUBLICATIONS

"Nonsurgical Placement of Arterial Endoprotehses: A New Technique Using Nitinol Wire", Cragg et al., *Radiology*, 147, 261–263, 1983.

"Metals That Remember", Steven Ashley, *Popular Science*, Jan. 1988.

"The Biocompatibility of Nitinol", L. S. Castleman et al., *Biocompatibility of Clinical Implant Materials*, chap. 5, pp. 129–154.

"Nonsurgical Implantation of a Vascular Ring Prosthesis Using Thermal Shape Memory Ti/Ni Alloy (Nitinol Wire)", Yoichi Sugita et al., vol. XXXII, *Trans Am Soc Artif Intern Organs*, 1986.

"Transluminal Expandable Nitinol Coil Stent Grafting: Preliminary Report"; Charles T. Dotter, M.D. et al., *Radiology* 147: 259–260, Apr. 1983.

"A New Percutaneous Vena Cava Filter", Andrew Cragg et al., *AJR*141, 601–604, Sep. 1983.

"Transvenous Atrial Septal Defect . . . ", Sideris et al., Abstract from the American Heart Assoc. Mtg., Nov. 1988.

"A Trial Septal Defects: Anatomic Study . . . ", Rome et al., Abstract from the American Heart Assoc. Mtg., Nov. 1988.

"Nonsurgical Closure of PDA: Clinical Application of the Rashkind PDA Occluder System", Rashkind et al., *Circulation*, vol. 75, No. 3, Mar. 1987.

"Percutaneous Catheter Closure of the Ductus Arteriosus in Children and Young Adults", *A.J.C.* 64, Jul. 1989.

"Outpatient Closure of the Patent Ductus Arteriosus", Wessel et al., *Circulation*, No. 5, May 1988.

"Transcatheter Umbrella Closure of Congential Heart Defect", Lock et al., *Circulation*, 75, No. 3, Mar. 1987.

"Transcatheter Closure of Atrial Septal Defects", Lock et al., *Circulation*, 79, No. 5, May 1989.

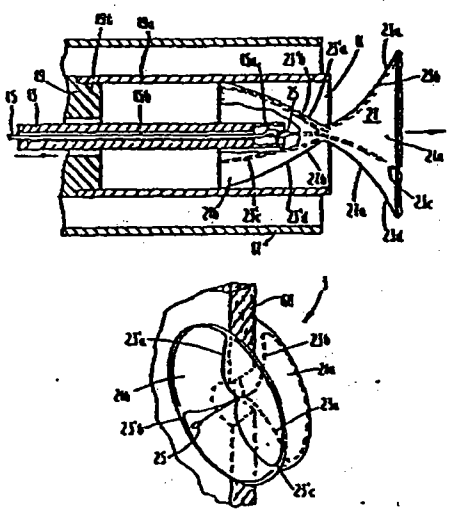
"Nonsurgical Therapy of Cardiac Disorder", Ruttenberg, *Pediatric Consult*, 5, No. 2, 1986.

Primary Examiner—Stephen C. Pellegrino
Assistant Examiner—Gary Jackson
Attorney, Agent, or Firm—Ratner & Prestia

[57] ABSTRACT

A device consisting of a wire for occluding an aperture within a body surface, such as atrial and ventricular septal defects (and the method of using such a device). The wire comprises two configurations, an elongated configuration for passage into said body through a catheter and through the aperture, and a preprogrammed configuration including occlusion-forming wire segments, one on each side of said aperture. The wire also includes means (preferably a temperature-induced shape change) for changing the wire from the elongated configuration to the preprogrammed configuration in the body.

14 Claims, 3 Drawing Sheets



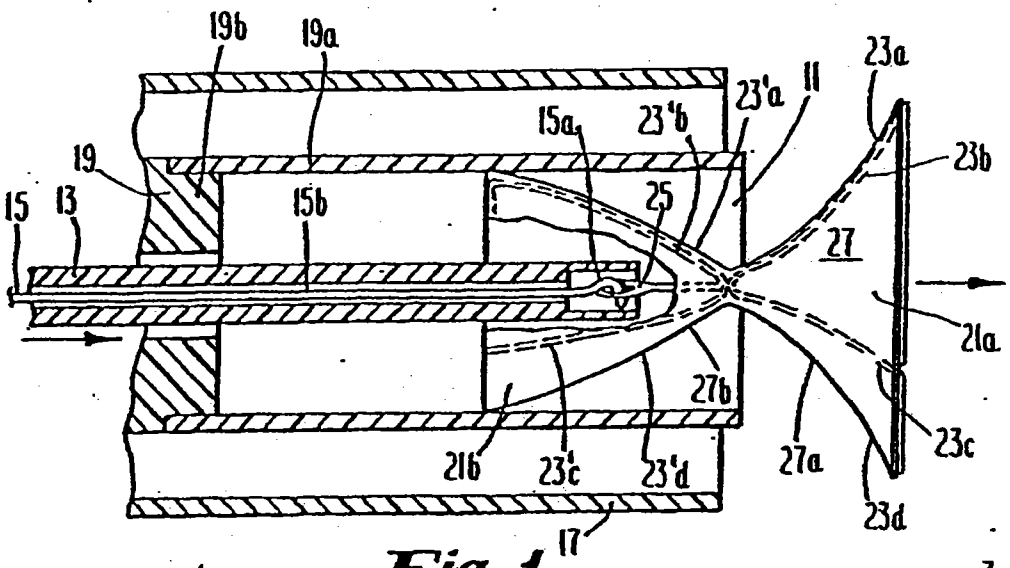


Fig. 1

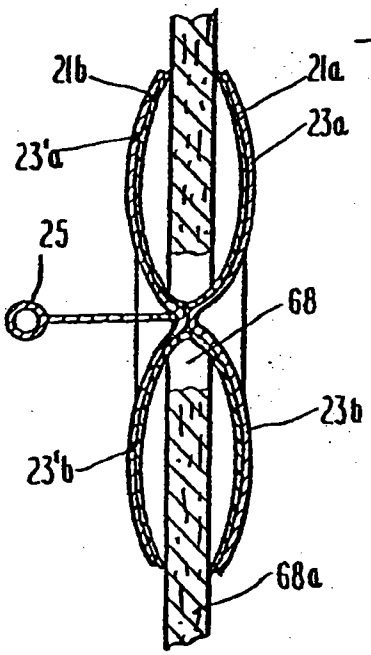


Fig. 5

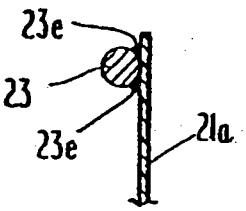


Fig. 4

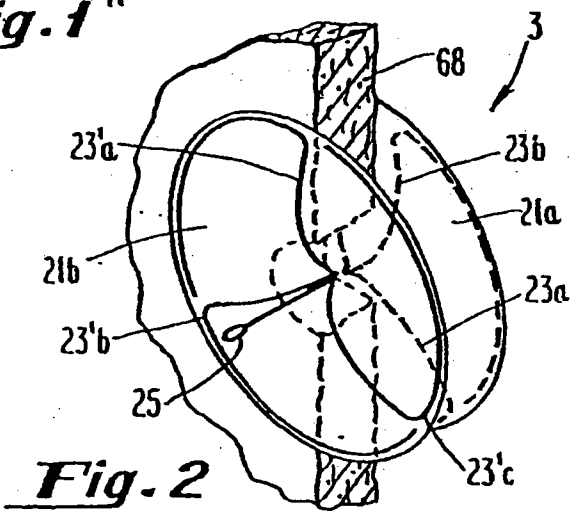


Fig. 2

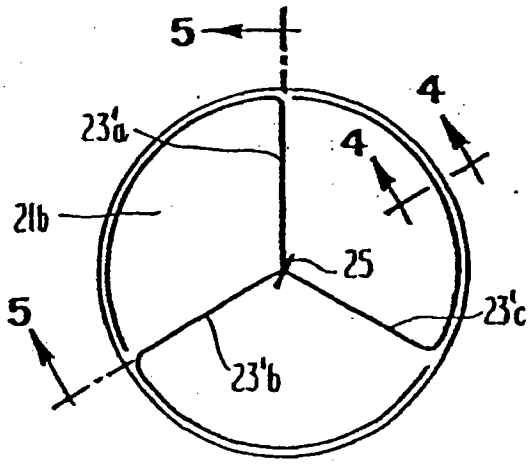


Fig. 3

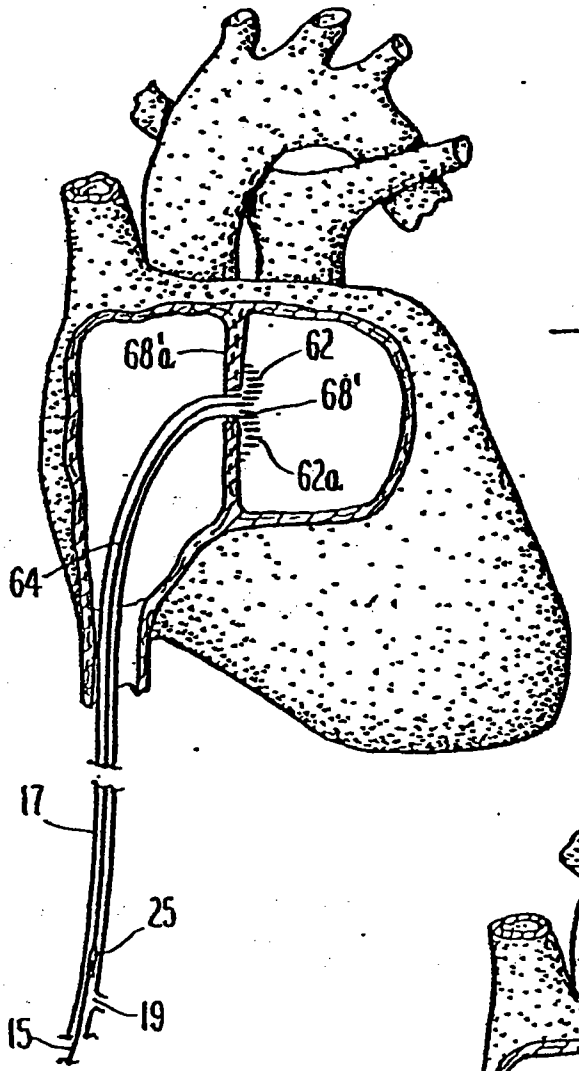


Fig. 6

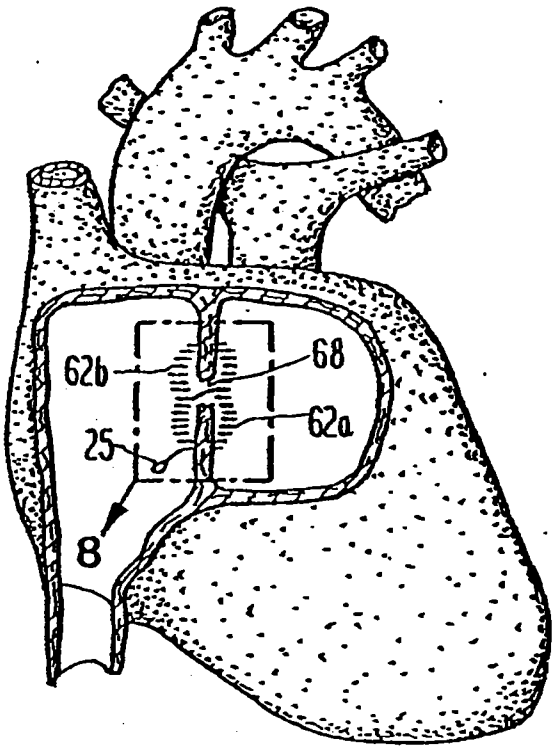


Fig. 7

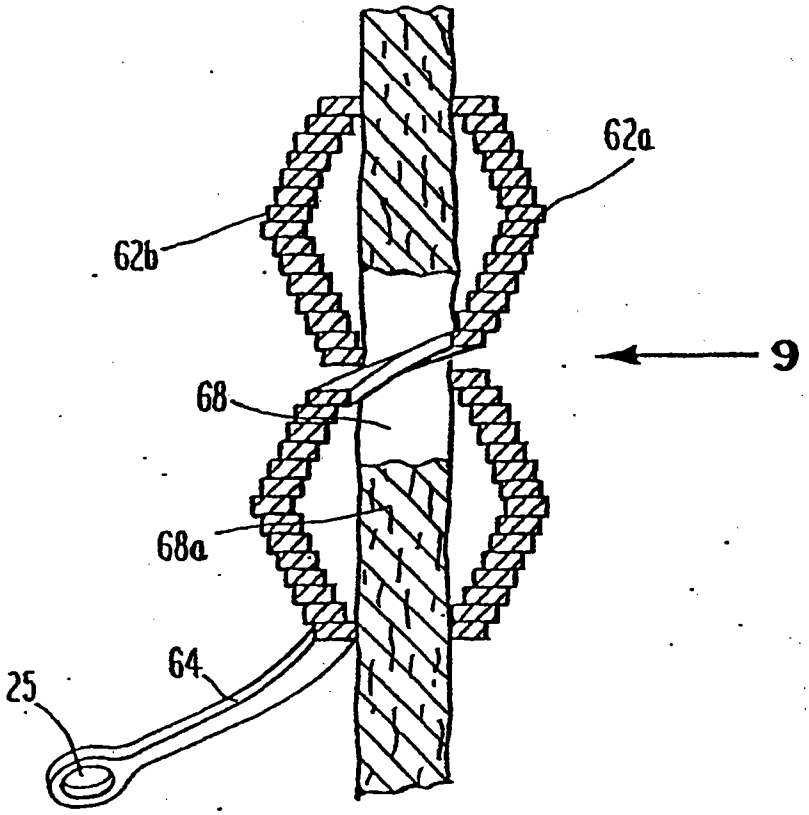


Fig. 8

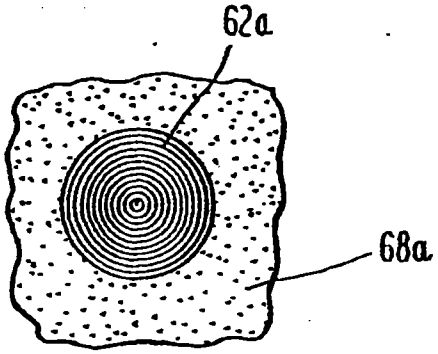


Fig. 9

APERTURE OCCLUSION DEVICE

FIELD OF THE INVENTION

The invention relates to devices and methods used to occlude (i.e. block blood flow through) an aperture within a body surface; specifically, it relates to devices and methods to occlude cardiovascular septal defects.

BACKGROUND OF THE INVENTION

It is often necessary to occlude a defect or an aperture within a body surface, such as a wall or membrane separating cavities within the body. A typical example is a congenital heart lesion called an atrial septal defect. This is a hole, between the two upper chambers of the heart, which must be closed.

King et al., U.S. Pat. No. 3,874,388, and Blake, U.S. Pat. No. 4,007,743 disclose a stainless steel apparatus for closing a shunt in the vascular system. The dual umbrella apparatus has six ribs which retain the umbrella in an open position. The King et al. apparatus has "barbs" at the ends of the ribs anchor onto the tissue surrounding the shunt. Alternatively, the barbs on the ribs of one umbrella may insert into holes on the ribs of the second umbrella, see FIG. 15A. The Blake apparatus has pivotally mounted struts which provide a flat surface to which a disk may be secured.

In "A New Percutaneous Vena Cava Filter", Cragg et al. disclose a filter composed of nitinol which when inserted into the inferior vena cava, traps emboli and clots. In the process of placing the filter, there is the threat of dislodging thrombi when the catheter or guide wire is advanced too far.

Lock et al., in *Circulation*, disclose a spring-loaded clamshell occluder of several sizes. The tension in the arms is manually controlled during delivery such that the arms of the distal umbrella, the one inserted first, are everted during placement, creating a cone.

The Rashkind occluder has two polyurethane foam disks mounted on surgical steel wire assemblies. The occluder is used to seal off the ductus arteriosus and is disclosed in *Circulation*, Vol. 75., page 583, *American Journal of Cardiology*, Vol. 64, page 218, and *Circulation*, Vol. 77, page 1068.

Devices currently used to occlude septal defects, including those indicated above, have been known to dislodge and embolize.

BRIEF DESCRIPTION OF THE INVENTION

The present invention comprises an aperture occlusion device which includes a wire having two configurations, an elongated configuration for passage through a catheter and through the aperture, and a second, preprogrammed, configuration. In the second configuration, two occlusion-forming wire segments oppose one another. These are adapted to be deployed on each side of the aperture to be occluded. A means for changing the wire from the elongated configuration to the preprogrammed configuration inside the body is further included. Typically, this may consist of a thermally responsive wire composition, the wire being preprogrammed so that at a certain temperature (body temperature for example), the wire, which is normally straight at other temperatures assumes a different ("preprogrammed") shape or configuration. Each occlusion-forming wire segment is adapted to press toward the opposing segment, thereby closing or occluding the aperture. Apertures or openings in other walls or membranes within the body or abnormally patent blood vessels may be similarly occluded.

In one embodiment, the occlusion-forming wire segments may comprise essentially flat helices, urged toward one another. In another embodiment, the wire may further include two foldable membranes, one associated with each occlusion-forming wire segment. The membranes are folded for transport through the catheter along with the wire. Upon conversion of the wire to its preprogrammed configuration, the membranes unfold onto a frame produced by the occlusion-forming wire segments, one on each side of the aperture.

Also included in the invention is a method for occluding an aperture by positioning a catheter at the distal side of the aperture and deploying a wire therethrough in an elongated configuration, (with the aid of a means for holding the wire) to the distal side of the aperture. Upon exiting the catheter, the wire converts to a preprogrammed configuration including an occlusion-forming wire segment on the distal side of the aperture. Upon continued deployment in the elongated configuration, the wire is permitted to assume the preprogrammed configuration including an opposing occlusion-forming wire segment on the proximal side of the aperture, with the two segments pressing toward one another. The wire is then disengaged from the means for holding the wire.

BRIEF DESCRIPTION OF THE FIGURES

FIG. 1 is a schematic cross-sectional view, during deployment, of one embodiment of the aperture occlusion device of the claimed invention;

FIG. 2 is a perspective view of another aperture occlusion device of the present invention in a fully deployed configuration;

FIG. 3 is planar view of the device shown in FIG. 2;

FIG. 4 is an enlarged cross-sectional view, in the plane 4—4 of FIG. 3;

FIG. 5 is a cross-sectional view, in plane 5—5, of the fully deployed aperture occlusion device shown in FIG. 3;

FIG. 6 is a perspective view of a heart, partially in cross-section, schematically showing an atrial septal defect and an occlusion device of the present invention partially deployed;

FIG. 7 is similar to FIG. 6, with the occlusion device fully deployed;

FIG. 8 is an enlarged cross-sectional view of the deployed aperture occlusion device shown in FIG. 7;

FIG. 9 is a planar view of the aperture occlusion device of FIG. 8.

DETAILED DESCRIPTION OF THE INVENTION

The invention includes devices and methods for occluding apertures in body surfaces, such as walls or membranes; the devices are adapted to be passed into the body through a catheter and through the aperture. Such apertures are openings, often congenital defects, connecting two cavities of the body. Fallopian tubes may also be occluded by using the devices and methods of the claimed invention. Cardiac septal defects are the type of apertures for which the preferred embodiments of the invention are designed. For example, the devices and methods of the present invention may be used to occlude a ventricular septal defect or an unwanted

vascular communication such as a patent ductus arteriosus.

An essential part of the present invention is a wire having two configurations, an elongated configuration or folded configuration for passage into the body through a catheter and through the aperture, and a preprogrammed configuration including occlusion-forming wire segments one on each side of the aperture. This wire also includes a means for causing it to change from the elongated configuration to the preprogrammed configuration inside the body. The device may also be combined with a catheter means for introducing the wire into the body. The catheter includes means for holding the wire, such as a release wire, while it is in the catheter and before it has been stimulated to convert to the preprogrammed configuration.

Preferably the wire is composed of a shape memory retentive material, such as nitinol, which causes the wire to change configurations, in response to a temperature change and which enables the wire to be activated at body temperature (having previously been at a different temperature) to assume a preprogrammed configuration. Spring steel may also serve this purpose. Furthermore, the wire must be biocompatible, and may be coated with Teflon, fibrin or endothelial cells, for example.

The occlusion forming wires may be associated with a foldable membrane, either by being embedded in the membrane or secured (by glue, stitches, staples or the like) to the surface thereof. In this embodiment, the membrane is transportable through a catheter in a folded configuration along with the wire. The occlusion-forming wires are adapted, upon converting to preprogrammed configuration, to unfold the membranes and to form a frame to support the membranes as domed or umbrella-shaped members on each side of the aperture. In another embodiment, the occlusion-forming wire is not attached to a membrane, and forms coiled helices, one on either side of the defect and urged toward each other.

Referring to FIG. 1, there is shown a partially deployed stage of one aperture occlusion device. As would be used for the occlusion of a septal defect, sheath 17 (a large catheter), after entering the body in a conventional manner, such as through a femoral vein, enters the heart via the inferior vena cava and is positioned on the distal side of an atrial septal defect in the body of the left atrium.

Release wire 15, including shaft 15*b* and knuckle 15*a*, device engaging catheter 13 and aperture occlusion device 27, all disposed within deployment catheter 19, are prepared as a unit prior to deployment through sheath 17 and introduced into the body either along with or later through sheath 17.

Aperture occlusion device 27 is composed of two biocompatible membranes 21*a* and 21*b*, each comprised of a thin polyurethane membrane film, for example. Preprogrammed shape memory retentive, wire ribs 23 and 23' are secured (and may be threaded, sewn or sandwiched) to each biocompatible membrane 21*a* and 21*b*. Eye 25, attached to wire ribs 23 and 23', extends from the center of aperture occlusion device 27 and engages knuckle 15*a* of release wire 15. One half of aperture occlusion device 27*b* is seen in the folded state; upon release from deployment catheter 19 and contact with body temperature, the membrane expands between the ribs, as shown by device half 27*a* with associated ribs 23. In FIG. 1, four wire ribs, 23*a–d* and 23'*a–d*, on each half of device 27, unfold, i.e. are converted from their elongated configuration to a second preprogrammed configuration, such as by a thermally stimulated shape change to a preprogrammed configuration, which urges the wire ribs outwardly, to expand and release. For this purpose, ribs 23*a–d* and 23'*a–d* are composed of a thermally responsive shape, shape memory retentive material, such as nitinol.

For transport to the site of deployment, the unit including release wire 15, device engaging catheter 13 and aperture occlusion device 27 are channeled into pod 11 of deployment catheter 19. Deployment catheter 19 includes an inner plastic portion 19*b* integrally connected to outer metal portion 19*a*. Release wire 15, device engaging catheter 13 and aperture occlusion device 27 are retained together and folded in deployment catheter 19. In practice, device 27 may be deployed without the use of deployment catheter 19, so long as sheath 17 is in a cold environment thus prohibiting device 27 from forming the preprogrammed shape.

In use, the assembly including release wire 15, device engaging catheter 13, aperture occlusion device 27 and deployment catheter 19 are passed through sheath 17 until the distal half of device 27 is disposed on the distal side of the septal defect (i.e. "aperture") to be occluded. Device engaging catheter 13, release wire 15, and aperture occlusion device 27 are maintained in place on the distal side of the defect while sheath 17 is retracted back through the defect to the proximal side thereof. Device engaging catheter 13 and release wire 15 are advanced freeing 27*a* to expand to preprogrammed shape. This enables a thermally stimulated shape change to the preprogrammed deployed configuration of ribs 23*a–d*. One-half of aperture occlusion device, 27*a*, is thus deployed on the distal side of the septal defect.

Coincident with the pull-back movement of deployment catheter 19 either in the preceding step or in the following step, sheath 17 is also retracted away from the aperture to be occluded.

Aperture occlusion device 27 is then pulled taut against the defect such that four wire ribs 23*a–d* expand and contact the heart tissue around the defect. Optionally, sheath 17 is then pulled back further away from the proximal side of the defect (if that had not been done earlier), and deployment catheter 19 is retracted leaving device engaging catheter 13, release wire 15, and aperture occlusion device 27 in place and thus exposing aperture occlusion device half 27*b* on the proximal side of the defect, at which point the second half 27*b* of device 27 is deployed.

Once aperture occlusion device 27 is fully deployed, as seen in FIGS. 2–5, knuckle 15*a* is disengaged from eye 25 of aperture occlusion device 27, by retracting catheter 13 slightly from eye 25. The assembly including deployment catheter 19, device engaging catheter 13 and release wire 15 are then retracted from sheath 17. Finally, sheath 17 is also retracted from the body.

FIG. 2 depicts a perspective view of an aperture occlusion device, with 3 ribs, like that seen in FIG. 1, but fully deployed to occlude a defect or aperture 68 in wall 68*a*. Membranes 21*a* and 21*b* are supported by wire ribs 23*a–c* and 23'*a–c* respectively, which urge the membranes toward each other and connect the membranes with eye 25.

As seen in FIG. 3, membrane 21*a* is attached to three wire ribs 23*a*, *b* and *c* extending circumferentially then curving and radially extending to the center of membrane 21*a*. Ribs 23*a–c* attach at the center of membrane

21*a* and connect the pair to each other and to eye 25 which attaches to a release wire, not shown. Ribs 23*a–c*, upon thermal triggering of the memory retentive properties of the rib material (preferably nitinol), support and maintain the shape of membrane 21*a*. Membrane 21*b* is similarly retained by ribs 23'*a–c*.

FIG. 4 is a cross-section through plane 4—4 of FIG. 3. As depicted therein, membrane 21*a* is secured to rib 23*a* by glue 23*e*. Stitches, staples or the like may also be used to affix membrane 21*a* to rib 23*a*. Other configurations of ribs 23*a, b, c* may also be used.

FIG. 5 illustrates a cross-section along plane 5—5 of the aperture occlusion device of FIG. 3. Membranes 21*a* and 21*b* occlude aperture 68 in wall 68*a*, and are supported by wire ribs, 23*a, b* and 23'*a, b*, which urge the membranes toward each other and connect the membranes with eye 25.

FIG. 6 depicts septal defect 68' with a double helix occlusion device 62 partially deployed. Device 62 is introduced as a straight wire 64 through the assembly including, device engaging catheter 13 (like that shown in FIG. 1, but not shown in FIG. 6 due to limited space available), release wire 15 and sheath 17. Sheath 17 is diametrically larger than device engaging catheter 13 to allow passage of device engaging catheter 13 therethrough. As with the assembly shown in and described with respect to FIG. 1, the assembly of release wire 15, device engaging catheter 13, wire 64 and sheath 17 are introduced through a large vein to and through the defect to be occluded. Sheath 17 optionally may be stopped short of defect 68' and may be withdrawn with device engaging catheter 13, as described, or independently of catheter 13.

Helix 62*a* is formed on the distal side of defect 68', preferably by the coiling of wire 64, nitinol for example, in response to a temperature change, upon body temperature contact or by retraction of spring steel into its "relaxed" (preprogrammed) configuration. A plurality of coils of progressively smaller diameter are formed, finally contacting the periphery of atrial wall 68*a*' surrounding defect 68' on the distal side thereof; each such coil of wire 64 contacts the previously formed coil above and below defect 68', such that helix 62*a* is deployed from the outside in, (relative to defect 68), until helix 62*a* is formed (as seen in FIG. 6).

The aperture occlusion device of FIG. 6 after deployment into the left atrium is seen in FIG. 9. The concentric circles are the result of the coiling of wire 64 (in this case from a very small starting circumference out) and also contacting the previously formed coil above and below defect 68', this time on the proximal side thereof.

After deploying helix 62*a* on the distal side of defect 68, sheath 17, device engaging catheter 13, release wire 15, and wire 64 are withdrawn equally and together to bring helix 62*a* into firm contact with the septal surface. As tension is maintained on wire 64 via release wire 15, sheath 17 is withdrawn over wire 64 and release wire 15, thereby exposing a length of wire 64 on the proximal side of the defect. Tension on wire 64 is then slowly reduced by advancing release wire 15 and sheath 17 equally and together. Wire 64 begins coiling at or near septal surface below defect 68. By progressively reducing tension on wire 64 (by repetitively withdrawing sheath 17 over release wire 15 and advancing sheath 17 and release wire 15 equally and together), successive coils are formed, each moving outward beyond the previously formed coil. Thus, helix 62*b* is formed from the inside out, until helix 62*b* is fully deployed as seen in FIGS. 7 and 8. Eye 25 is then disengaged from the release wire 15 (not shown), and the remaining apparatus is removed from the body as described with respect to FIG. 1.

In those embodiments dependent upon a thermally responsive change (such as with nitinol) as the means for effecting device deployment, it is desirable prior to deployment to continuously infuse a biocompatible fluid (such as normal saline) which is substantially below body temperature (for example at room temperature) through side port 19 of sheath 17 to maintain a thermal environment within sheath 17, that is below the transition temperature of the thermally responsive wire 64. This assures that wire 64 will not assume its programmed shape until it exits sheath 17.

Furthermore, the programmed deployed configuration of the double helix coil (in the embodiment of FIGS. 6–9) may preferably include shaping to urge the outermost coils of helices 62*a* and 62*b* inward toward the septal surface (and one another) to provide an increased frictional force between the helices and their respective septal surfaces.

By way of general description of the method of this invention, the device of the present invention may be used in a method of occluding an aperture within a body surface. A catheter, which can accommodate a wire in an elongated or folded configuration (optionally with an associated membrane), is introduced through a body member such as a femoral vein, deployed, for example, into the heart through the inferior vena cava and manipulated into position on the distal side of the aperture where the wire assumes its preprogrammed configuration including an occlusion-forming wire segment urged toward the aperture on the distal side of the septal defect. Withdrawing the catheter partially over the wire allows a substantial length of the wire to be exposed on the near side of the defect. Upon further deployment, the wire assumes a preprogrammed configuration including an occlusion-forming wire segment urged toward the aperture on the proximal side of the aperture. The wire is then disengaged from the means for holding it.

The device and method of this invention are believed to be particularly well adapted to occlude both atrial and ventricular septal defects, as well as other cardiovascular openings, such as a patent ductus arteriosus. The device (modified for tubal rather than aperture occlusion) is also well suited for use in occluding fallopian tubes.

In the embodiments disclosed, the finished structure comprises two connected occlusion-forming wire segments, disposed on opposite sides of an aperture, each formed of a wire resulting in helices, or domed members (with membranes attached to a wire frame), urged toward one another.

While this invention has been disclosed with reference to specific embodiments, it is apparent that other embodiments and equivalent variations of this invention may be devised by those skilled in the art without departing from the true spirit and scope of this invention. The appended claims are intended to be construed to include all such embodiments and equivalent variations.

What is claimed is:

1. A device adapted to occlude an aperture within a body surface, and adapted to be passed into said body, through a catheter and through said aperture, said device comprising a wire having two configurations, an elongated configuration for passage through said cathe-

ter and through said aperture, and a preprogrammed configuration which includes occlusion-forming wire segments one on each side of said aperture urged toward one another and means for causing said wire to change from said elongated configuration to said preprogrammed configuration inside said body, said means being a temperature responsive material of construction of said wire, by which said wire is activated at body temperature, to assume said preprogrammed configuration.

2. A device of claim 1 wherein said wire is combined with a catheter means for introducing said wire into said body, said catheter means also includes means for holding said wire, while it is in said catheter, at a temperature at which said wire does not tend to assume said preprogrammed configuration.

3. A device of claim 1 wherein said occlusion-forming segments each comprise helical coils urged toward one another.

4. A device of claim 1 wherein said wire further includes two foldable membranes, one associated with said first occlusion-forming wire segment and the other associated with said second occlusion-forming wire segment, said membranes in folded configuration being transportable through a catheter along with said wire, said wire adapted upon converting from said elongated configuration to said preprogrammed configuration to unfold said membranes and to form a frame supporting said membranes as essentially planar members, one disposed on each side of said aperture, and urged toward one another, wherein said means for causing a change in configuration is a thermally responsive material of construction.

5. A device according to claim 4 wherein said wire is secured to said membranes of said occlusion-forming wire segments.

6. A device according to claim 1, wherein said wire consists of nitinol.

7. A device according to claim 1, wherein said wire is biocompatible.

8. A device according to claim 1, wherein said wire is coated to enhance biocompatibility.

9. A device adapted to occlude an aperture within a body surface, and adapted to be passed into said body, through a catheter and through said aperture, said device comprising a wire having two configurations, an elongated configuration for passage through said catheter and through said aperture, and a preprogrammed configuration which includes occlusion-forming wire segments one on each side of said aperture, and means for causing said wire to change from said elongated configuration to said preprogrammed configuration inside said body, wherein said occlusion forming segments each comprise helical coils urged toward one another.

10. A device according to claim 9, wherein said wire consists of spring steel.

11. A method for occluding an aperture within a body surface by positioning the end of a catheter at the distal side of the aperture, deploying a wire of temperature responsive material of construction in an elongated configuration through said catheter to the distal side of said aperture with the aid of a means for holding said wire, permitting the wire exposed thereby to assume a preprogrammed configuration, including an occlusion-forming wire segment on the distal side of said aperture, and urged toward said aperture, withdrawing the end of said catheter through said aperture and deploying an additional length of said wire in an elongated configuration to be exposed on the proximal side of said aperture, whereupon said continued deployment, said wire is permitted to assume a preprogrammed configuration, including an opposing occlusion-forming wire segment urged toward said aperture on the proximal side of the aperture, and disengaging the wire from the means for holding said wire.

12. A method as recited in claim 11, wherein said defect is a atrial septal defect.

13. A method as recited in claim 11, wherein said defect is a ventricular septal defect.

14. A method as recited in claim 11, wherein said defect is a patent ductus arteriosus.

* * * * *

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

NITINOL MEDICAL TECHNOLOGIES, INC. and LLYOD A. MARKS,

Plaintiff,

v.
vi.

AGA MEDICAL CORPORATION,

Defendants.

Civ. No. 98 CV 12506NG

DEFENDANT'S ANSWER, COUNTERCLAIMS, AND JURY DEMAND

Defendant AGA Medical Corporation, in response to Plaintiffs' Complaint against it, hereby alleges, pleads, and claims as follows:

DEFENDANT'S ANSWERS TO THE COMPLAINT

1. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in ¶ 1, and therefore denies the same.

2. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in ¶ 2, and therefore denies the same.

3. Defendant admits the allegations set forth in ¶ 3.

4. Defendant admits that Plaintiffs purport to bring a claim under Title 35 of the United States Code but denies that Plaintiffs' Complaint states a claim for relief and admits the remaining allegations contained in ¶ 4 of Plaintiffs' Complaint.

5. As to ¶ 5, Defendant admits that venue is proper but denies that Plaintiffs' Complaint states a claim for which relief may be granted.

6. Defendant admits that U.S. Patent No 5,108,420 was attached to the Complaint as Exhibit A, but lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in ¶ 6, and therefore denies the same.

7. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in ¶ 7, and therefore denies the same.

8. Defendant denies the allegations contained in ¶ 8 of Plaintiffs' Complaint.

9. Defendant denies the allegations contained in ¶ 9 of Plaintiffs' Complaint.

10. Defendant denies the allegations contained in ¶ 10 of Plaintiffs' Complaint.

11. Defendant denies that Plaintiffs are entitled to any of the relief requested in Plaintiffs' Complaint.

12. Defendant denies each and every allegation of Plaintiffs' Complaint except as expressly admitted herein.

AFFIRMATIVE DEFENSES

As affirmative defenses to Plaintiffs' Complaint, Defendant alleges as follows:

13. Plaintiffs' Complaint fails to state a claim for which relief can be granted.

14. With respect to any claims of the patent in suit, under the Doctrine of Prosecution History Estoppel, Plaintiffs are barred from asserting an interpretation of the claims which is inconsistent with arguments and amendments made to the claims during the application process for the patent.

15. U.S. Patent No. 5,108,420 is invalid and void under Title 35 U.S.C. §102.

16. U.S. Patent No. 5,108,420 is invalid and void under Title 35 U.S.C. §103.

17. U.S. Patent No. 5,108,420 is invalid and void under Title 35 U.S.C. §112.

18. Defendant has not and is not now infringing U.S. Patent No. 5,108,420.

19. The doctrine of estoppel bars Plaintiffs from now asserting that Defendant is infringing U.S. Patent No. 5,108,420.

20. The doctrine of waiver bars Plaintiffs from now asserting that Defendant is infringing U.S. Patent No. 5,108,420.

21. The doctrine of laches prevents Plaintiffs from now asserting that Defendant is infringing U.S. Patent No. 5,108,420.

REQUEST FOR RELIEF FROM THE COMPLAINT

WHEREFORE, Defendant respectfully requests that the Complaint be dismissed with prejudice, that Defendant be awarded its reasonable attorneys' fees and costs and that the Court award Defendant such other and further relief as the Court may deem just and proper.

COUNTERCLAIMS OF DEFENDANT

1. Counterclaim Plaintiff AGA Medical Corporation is a Minnesota corporation, having its principal place of business in Golden Valley, Minnesota.

2. Upon information and belief Nitinol Medical Technologies, Inc. ("Nitinol") is a corporation having its principal place of business in Boston, Massachusetts.

3. This action arises under the laws of the United States, more particularly under 35 U.S.C. §§ 1 et seq and 35 U.S.C. §§ 1051 et seq.

4. These Counterclaims seek a declaratory judgment under the provisions of 28 U.S.C. §§ 2201 and 2202.

5. This court has jurisdiction over these Counterclaims pursuant to Fed.R.Civ.P. 13(a) and (b), 15 U.S.C. §1121 and 28 U.S.C. §§ 1338(a) and 1338(b).

6. Venue is proper in this district pursuant to 28 U.S.C. §§ 1331, 1338, and 1400.

7. AGA Medical Corporation requests a declaratory judgment of invalidity, unenforceability and non-infringement of U.S. Patent No. 5,108,420 (the '420 patent).

8. Upon information and belief, and pursuant to the representations in Mark and Nitinol's complaint, Defendants' Nitinol and Marks have standing to bring this cause of action against AGA Medical Corporation for patent infringement of the '420 patent.

9. Prior to December 1, 1997, Nitinol Medical Technologies, Inc. attempted to purchase AGA Medical Corporation and its technology related to intravascular occlusion devices.

10. Prior to December 1,1997, AGA Medical Corporation refused to sell the company and its technology to Nitinol Medical Technologies, Inc.

11. On or about December 19, 1997 in a letter from a person identified as the President and CEO of Nitinol Medical Technologies, Nitinol asserted that if AGA Medical Corporation manufactured used or sold its occluding devices in the U.S., AGA Medical Corporation would first have to obtain rights under U.S. Patent No. 5,108,420.

12. In a letter dated January 21, 1998, counsel for AGA Medical Corporation responded to Nitinol's letter dated December 19, 1997, identifying elements claimed and required by U.S. Patent No. 5,108,420 that are completely absent from AGA Medical Corporation's devices.

13. The letter dated January 21, 1998 from AGA Medical Corporation's counsel stated that:

"In view of the above, we have concluded that the issues raised in your December 19, 1998 letter are moot. If after reviewing the above, you continue to believe that in order to make, use, or sell the Amplatzer™ Septal Occluder in the United States it will be necessary to obtain rights under

the '420 patent, then a claim chart or some other detailed comparison from you comparing the independent claims of the '420 patent and the Amplatzer™ Septal Occluder would be helpful so that we can fully understand your position in this matter."

14. Nitinol then began using commercial advertising and/or promotions in commerce that included false and/or misleading representations of the nature, characteristics and/or qualities concerning products of AGA Medical Corporation.

15. Nitinol has distributed in interstate commerce promotional materials that are false or misleading.

16. Nitinol has posted false or misleading promotional materials on its web site.

17. Nitinol continues to unfairly compete with AGA Medical Corporation.

18. Counsel for Nitinol did not respond to the letter dated January 21, 1998 from AGA Medical Technologies' counsel until almost one (1) year later, on or about December 10, 1998. On or about December 10, 1998 counsel for Nitinol mailed a copy of the subject Complaint that had apparently been filed in the United States District Court, District of Massachusetts on December 10, 1998.

19. Counterclaimant Defendants have charged AGA Medical Corporation with infringement of the '420 patent, an allegation which AGA Medical Corporation has denied. AGA Medical Corporation further alleges that the '420 patent is invalid, void and unenforceable.

20. An actual and justiciable controversy exists between AGA Medical Corporation and Defendants with respect to the alleged infringement, validity and enforceability of the '420 patent.

21. AGA Medical Corporation has not and is not infringing the '420 patent.

22. The '420 patent is invalid and unenforceable under 35 U.S.C. § 102 because the claimed subject matter is anticipated by prior art; under 35 U.S.C. § 103 for obviousness; and under 35 U.S.C. § 112 for indefiniteness.

23. Nitinol's false and misleading promotional materials has caused damage to AGA Medical Corporation.

COUNTERCLAIM I

24. Paragraphs 1 through 23 are incorporated as if fully rewritten herein.

25. Plaintiffs have charged Defendant with infringement of the '420 patent, an allegation which Defendant denies.

26. An actual and justiciable controversy exists as between Plaintiff and Defendant with respect to the alleged infringement, validity and enforceability of the '420 patent.

27. The '420 patent is invalid, void and unenforceable under:

(a) 35 U.S.C. §102 because the claimed subject matter is anticipated by prior art references;

(b) 35 U.S.C. §103 for obviousness; and

(c) 35 U.S.C. §112 for indefiniteness.

28. Defendant requests declaratory judgment of invalidity, unenforceability and non-infringement of United States Patent No. 5,108,420 (the '420 patent).

COUNTERCLAIM II

29. Paragraphs 1 through 28 are incorporated as if fully rewritten herein.

30. Nitinol's actions, particularly as alleged in paragraphs 14 through 17 above, have

occurred in or had a substantial effect upon interstate commerce, and constitute false or misleading descriptions or representations of fact in commercial advertising or promotion, which misrepresent the nature, characteristics or qualities of Nitinol's goods and/or AGA Medical Corporation's goods in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

31. As a direct and proximate result of Nitinol's actions, AGA Medical Corporation has been and continues to be injured in an amount yet to be determined.

32. Unless enjoined by this Court, Nitinol will continue its actions in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), to AGA Medical Corporation's substantial and irreparable damage.

COUNTERCLAIM III

33. Paragraphs 1 through 32 are incorporated as if fully rewritten herein.

34. At all times relevant hereto, Nitinol and AGA Medical Corporation have been engaged in the conduct of trade or commerce in the Commonwealth of Massachusetts.

35. Nitinol's actions, particularly as alleged in paragraphs 14 through 17 above, have occurred primarily or substantially in Massachusetts, and constitute unfair or deceptive acts or practices in the conduct of trade, in violation of M.G.L.A. c. 93A, § 11.

36. On information and belief, the unfair or deceptive acts or practices of Nitinol have been committed willfully and knowingly by Nitinol.

37. As a direct and proximate result of Nitinol's unfair or deceptive acts or practices, AGA Medical Corporation has been and continues to be injured in an amount yet to be determined.

38. Unless enjoined by this Court, Nitinol will continue its actions in violation of

M.G.L.A. c. 93A, § 11, to AGA Medical Corporation's substantial and irreparable damage.

PRAYER FOR RELIEF

WHEREFORE, Defendant prays for judgment on its Counterclaims as follows:

A. That this Court declare 1) that AGA Medical Corporation has not infringed any of the claims of U.S. Patent No. 5,108,420 and 2) that U.S. Patent No. 5,108,420 is invalid, void and unenforceable;

B. That this Court concludes as a matter of law that Nitinol, by its actions, has violated Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and has violated M.G.L.A. c. 93A, § 11, to the substantial and irreparable damage of AGA Medical Corporation;

C. That Nitinol, its officers, directors, employees, agents, servants, successors and assigns, and any and all persons acting in privity or concert with it, be and are preliminarily and permanently restrained and enjoined from engaging in any further acts or conduct in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and/or in violation of M.G.L.A. c. 93A, § 11;

D. That AGA Medical Corporation recover all damages sustained as a result of Nitinol's violations of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and/or in violation of M.G.L.A. c. 93A, § 11, and that the damages so found be multiplied to the extent provided in said statute(s);

E. That AGA Medical Corporation be awarded its reasonable costs and attorneys' fees sustained as a result of this action; and

F. That AGA Medical Corporation be awarded such other and further relief as this Court may deem just and proper.

A JURY IS DEMANDED FOR ALL ISSUES TRIABLE TO A JURY

AGA MEDICAL CORPORATION

By Its Attorneys,

Dated: 4-12-99

Thomas C. O'Konski, Esq. (BBO # 378265)
Michael R. Reinemann, Esq. (BBO # 556,308)
Cesari and McKenna, L.L.P.
30 Rowes Wharf
Boston, Massachusetts 02110
(617) 951-2500

Of Counsel:

Paul T. Dietz, Esq.
Nikolai, Mersereau & Dietz, P.A.
900 Second Avenue South, Suite 820
Minneapolis, Minnesota 55402
(612) 339-7461

CERTIFICATE OF SERVICE

I hereby certify that a true copy of the foregoing, Defendant's Answer, Counterclaims, and Jury Demand was:

_____ sent via facsimile;

_X_ hand-delivered;

_____ mailed via First Class mail, postage prepaid;

to William G. McElwain of HALE and DORR, LLP, Attorneys for Plaintiff/Counterclaim Defendant, 60 State Street, Boston, Massachusetts 02109, on this 12th day of April, 1999.

Thomas C. O'Konski, Esq.

EXHIBIT C

JS 44 (Rev. 3/99)

CIVIL COVER SHEET 04-4486 JMR FLN

The JS-44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

AGA MEDICAL CORPORATION

DEFENDANTS

NITINOL MEDICAL TECHNOLOGIES, INC.
d/b/a NMT Medical, Inc. and
Lloyd A. Marks

(b) County of Residence of First Listed Plaintiff Hennepin
(EXCEPT IN U.S. PLAINTIFF CASES)

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

(c) Attorney's (Firm Name, Address, and Telephone Number)
James T. Nikolai (#0144101)
NIKOLAI & MERSEREAU, P.A.
900 Second Avenue South, #820
Minneapolis, MN 55402
612-339-7461

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff (For Diversity Cases Only) and One Box for Defendant)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	1	Incorporated or Principal Place of Business In This State	☐ 4	4
Citizen of Another State	☐ 2	2	Incorporated and Principal Place of Business In Another State	☐ 5	5
Citizen or Subject of a Foreign Country	☐ 3	3	Foreign Nation	☐ 6	6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
	PERSONAL INJURY	PERSONAL INJURY			
☐ 110 Insurance	☐ 310 Airplane	☐ 362 Personal Injury—Med. Malpractice	☐ 610 Agriculture	☐ 422 Appeal 28 USC 158	☐ 400 State Reapportionment
☐ 120 Marine	☐ 315 Airplane Product Liability	☐ 365 Personal Injury—Product Liability	☐ 620 Other Food & Drug	☐ 423 Withdrawal 28 USC 157	☐ 410 Antitrust
☐ 130 Miller Act	☐ 320 Assault, Libel & Slander	☐ 368 Asbestos Personal Injury Product Liability	☐ 625 Drug Related Seizure of Property 21 USC 881		☐ 430 Banks and Banking
☐ 140 Negotiable Instrument	☐ 330 Federal Employers' Liability		☐ 630 Liquor Laws	PROPERTY RIGHTS	☐ 450 Commerce/ICC Rates/etc.
☐ 150 Recovery of Overpayment & Enforcement of Judgment	☐ 340 Marine	PERSONAL PROPERTY	☐ 640 R.R. & Truck	☐ 820 Copyrights	☐ 460 Deportation
☐ 151 Medicare Act	☐ 345 Marine Product Liability	☐ 370 Other Fraud	☐ 650 Airline Regs.	☒ 830 Patent	☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)	☐ 350 Motor Vehicle	☐ 371 Truth in Lending	☐ 660 Occupational Safety/Health	☐ 840 Trademark	☐ 810 Selective Service
☐ 153 Recovery of Overpayment of Veteran's Benefits	☐ 355 Motor Vehicle Product Liability	☐ 380 Other Personal Property Damage	☐ 690 Other		☐ 850 Securities/Commodities/ Exchange
☐ 160 Stockholders' Suits	☐ 360 Other Personal Injury	☐ 385 Property Damage Product Liability	LABOR	SOCIAL SECURITY	☐ 875 Customer Challenge 12 USC 3410
☐ 190 Other Contract			☐ 710 Fair Labor Standards Act	☐ 861 HIA (1395ff)	☐ 891 Agricultural Acts
☐ 195 Contract Product Liability			☐ 720 Labor/Mgmt. Relations	☐ 862 Black Lung (923)	☐ 892 Economic Stabilization
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	☐ 730 Labor/Mgmt.Rptg.&Disclosure Act	☐ 863 DIWC/DIWW (405(g))	☐ 893 Environmental Matters
☐ 210 Land Condemnation	☐ 441 Voting	☐ 510 Motions to Vacate Sentence	☐ 740 Railway Labor Act	☐ 864 SSID Title XVI	☐ 894 Energy Allocation Act
☐ 220 Foreclosure	☐ 442 Employment	Habeas Corpus:		☐ 865 RSI (405(g))	☐ 895 Freedom of Information Act
☐ 230 Rent Lease & Ejectment	☐ 443 Housing/ Accommodations	☐ 530 General	☐ 790 Other Labor Litigation	FEDERAL TAX SUITS	☐ 900 Appeal of Fee Determination Under Equal Access to Justice
☐ 240 Torts to Land	☐ 444 Welfare	☐ 535 Death Penalty	☐ 791 Empl. Ret. Inc. Security Act	☐ 870 Taxes (U.S. Plaintiff or Defendant)	☐ 950 Constitutionality of State Statutes
☐ 245 Tort Product Liability	☐ 440 Other Civil Rights	☐ 540 Mandamus & Other		☐ 871 IRS—Third Party 26 USC 7609	☐ 890 Other Statutory Actions
☐ 290 All Other Real Property		☐ 550 Civil Rights			
		☐ 555 Prison Condition			

V. ORIGIN (PLACE AN "X" IN ONE BOX ONLY)

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION (Cite the U.S. Civil Statute under which you are filing and write brief statement of cause. Do not cite jurisdictional statutes unless diversity.)

Declaratory Judgment of Non-Infringement and Invalidity of U.S. Patent 5,108,420
28 U.S.C. 2201, 35 U.S.C. § 1 et seq.

VII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23 DEMAND $ CHECK YES only if demanded in complaint: JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE DOCKET NUMBER

DATE: October 13, 2004

SIGNATURE OF ATTORNEY OF RECORD: James T Nikolai

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

SCANNED OCT 14 2004 U.S. DISTRICT COURT MPLS

; 44 Reverse (Rev. 12/96)

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS-44

Authority For Civil Cover Sheet

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

AGA Medical Corporation.,

Plaintiff,

v.

Civil Action # 04-4486 JNE/FLN

Nitinol Medical Technologies, Inc.,
d/b/a/ NMT Medical, Inc, and
Lloyd A. Marks

Defendants.

COMPLAINT FOR DECLARATORY RELIEF

For its complaint against Nitinol Medical Technologies, Inc. ("NMT") and Lloyd A. Marks (hereinafter referred to collectively as "Defendants"), Plaintiff AGA Medical Corp. states and alleges as follows:

PARTIES

1. Plaintiff, AGA Medical Corp. ("AGA") is a corporation duly organized and existing under the laws of the State of Minnesota with its principal place of business in Golden Valley, Minnesota.

2. NMT is a corporation organized and existing under the laws of the State of Massachusetts, with its principal place of business in Boston, Massachusetts.

3. Lloyd A. Marks is a resident of the state of New Jersey.

JURISDICTION

4. This is a claim for, among other things, a declaratory judgment of patent invalidity and non-infringement.

5. This Court has jurisdiction over AGA's federal claims by virtue of the provisions of 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

6. This Court has personal jurisdiction over the Defendants. NMT knowingly and intentionally exploits the Minnesota market through advertising and sales of its products. Mr. Marks knowingly and intentionally exploits the Minnesota market through the royalties he receives under his exclusive licensing agreement with NMT.

VENUE

7. A substantial part of the events or omissions giving rise to AGA's cause of action occurred in this judicial district.

8. By reasons of the foregoing, venue of this action is proper in this Court pursuant to the provisions of 28 U.S.C. § 1391(b).

COUNT I: INVALIDITY AND NON-INFRINGEMENT OF PATENT

9. AGA restates Paragraphs 1-8 of this Complaint.

10. Lloyd A. Marks claims to be the owner of U.S. Patent No. 5,108,420 issued on April 28, 1992, attached hereto as Exhibit A (the "'420 Patent"). NMT claims to own an exclusive license under the '420 patent.

11. As a result of the acts set forth below, an actual justiciable controversy exists between Defendants and AGA with respect to the validity of the '420 Patent and Defendants' claims that AGA's products infringe the '420 Patent.

12. On December 10, 1998, Defendants commenced litigation in the U.S. District Court for the District of Massachusetts against AGA for infringement of the '420 Patent (hereinafter referred to as "the Massachusetts Litigation"). The Massachusetts Litigation was

captioned Nitinol Medical Tech v. AGA Medical Corp., 98-cv-12506-NG. A copy of the Complaint is attached hereto as Exhibit B.

13. On April 25, 2001, the District Court stayed the Massachusetts Litigation pending a reexamination of the '420 patent by the United States Patent and Trademark Office. A copy of the Order staying the Prior Litigation is attached hereto as Exhibit C. On December 1, 2003, the District Court of Massachusetts dismissed the litigation without prejudice. A copy of the Order dismissing the litigation is attached as Exhibit D.

14. During the reexamination of the '420 Patent, the Patent Office Examiner rejected the claims. However, on August 19, 2004, the Patent and Trademark Office Board of Appeals purportedly reversed the examiner's rejection.

15. On September 7, 2004, Defendants issued a press release in which John E. Ahern, the President and CEO of NMT declared:

> "[t]he Board of Appeals decision represents an important step in our patent infringement efforts against AGA. As a medical technology innovator, NMT Medical has developed and obtained the rights to an impressive portfolio of patents and intellectual property that we will continue to defend aggressively."

(emphasis added). A copy of the September 7th press release is attached as Exhibit E.

16. AGA's position has consistently been that it has not infringed the '420 Patent and that the '420 Patent is invalid and unenforceable.

17. By virtue of the exchanges outlined above, there is a substantial and continuing justiciable controversy between AGA and Defendants as to Defendants' rights in the '420 Patent, the validity and enforceability of the '420 Patent, and as to AGA's continuing right to make, use and sell its products.

18. AGA contends that the claims for the '420 Patent, including any claims which may have survived reexamination, are not infringed by AGA.

19. In the alternative, AGA contends that the claims for the '420 Patent, including any claims which may have survived reexamination, are invalid, unenforceable, and void since they have not and may not be duly or legally issued for many reasons including, without limitation, that each are invalid, unenforceable, and void given the statutory requirements of 35 U.S.C. §§ 102, 103 or 112 for one or more of the following reasons:

a. The patentee did not invent the subject matter patented, nor did he make any invention or discovery, either novel, original, or otherwise, within the meaning of United States Code, Title 35;

b. The alleged invention was made by another in this country before the patentee's alleged invention, and such other person had not abandoned, suppressed, or concealed it;

c. The patent does not particularly point out and distinctly claim the part, improvement, method, steps, or combination that the patentee claims as his invention, as required by Title 35, United States Code;

d. The specification does not contain a written description of the invention and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it most nearly connected, to make, construct, compound and/or use the same, and the description does not adequately explain the principle or the best mode in which the patentee contemplated applying the principle so as

to distinguish it from other inventions, as required by Title 35, United States Code;

e. The claims, and each of them, of the patent are excessively vague and indefinite and do not distinctly point out and define the invention;

f. The claims, and each of them, are not directed to patentable combinations, but are directed to mere aggregations of parts or steps, means, or elements which were matters of common knowledge in the art to which said patent relates before the alleged invention and more than one year prior to the date of the application for the patent;

g. In light of the prior art at the time the alleged invention was made, the subject matter as claimed in the patent would have been obvious to one skilled in the art to which the alleged invention relates and does not constitute patentable invention;

h. The alleged invention or discovery was disclosed in a U.S. patent to another, the application for which was filed before the alleged invention by the patentee of the Patents-in-Suit;

i. More than one year prior to the filing of the original application which matured into the Patents-in-Suit, the alleged invention was patented or described in printed

publications in this or in foreign countries, or was in public use, or on sale in this country;

j. Before the alleged invention or discovery of the patentee, the alleged invention was known or used by others than the alleged inventor and was on sale in this country and was patented or described in a printed publication in this or in foreign countries.

20. AGA further avers that any claims of the '420 Patent, including any claims which may have survived reexamination, which may be held to be valid are so restricted in scope that AGA has not infringed said claims.

21. As a result of the proceedings in the U.S. Patent and Trademark Office during the prosecution of the applications and reexamination proceedings for the '420 Patent and the admissions and representations made in the proceedings by or on behalf of the applicant, Defendants are estopped under the doctrine of prosecution history estoppel and may not now seek or maintain a construction for the claims of the '420 Patent, were the same otherwise possible, to cover or embrace any products made, used, or sold by AGA.

22. The Patent Statutes provide, in part, that during a reexamination proceeding in the Patent and Trademark Office "[n]o proposed amended or new claim enlarging the scope of a claim of the patent will be permitted in a reexamination proceeding..." 35 U.S.C. § 305 (2003). Because none of the original claims of the '420 patent cover AGA's products or conduct AGA cannot be found ti infringe any claim added or amended during reexamination.

23. AGA has not done any act or thing and is not proposing to do any act or thing in violation of any rights validly belonging to Defendants under any patent owned by Defendants.

The '420 Patent is invalid and unenforceable, and not infringed by AGA, and AGA is not liable for infringement of said patents.

PRAYER

WHEREFORE, AGA prays that:

1. Entry of judgment providing:

a. A declaration that Defendants is without right or authority to threaten or maintain suit against AGA for alleged infringement of the '420 Patent, including any claims which may have survived reexamination.

b. A declaration that the claims of '420 Patent, including any claims which may have survived reexamination, are invalid, unenforceable and void in law.

c. A declaration that the claims of '420 Patent, including any claims which may have survived reexamination, are not infringed by AGA.

d. AGA be awarded its costs and attorneys fees related to this suit.

e. Preliminary and permanent injunctive relief enjoining Defendants, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with it who receive actual notice of the injunction from initiating infringement litigation or threatening AGA or any of its customers, dealers, agents, servants, or employees, or any perspective or present sellers, dealers, or users of AGA's products, with infringement litigation, or charging any of them verbally or in writing with infringement of the '420 Patent because of the manufacture, use, sale, or offering for sale of the AGA's products.

2. All other relief that the Court may deem appropriate.

Respectfully submitted,

Dated: October 13, 2004

NIKOLAI & MERSEREAU, P.A.

James T. Nikolai (#0144101)
Peter G. Nikolai (#0322052)
900 Second Avenue South
820 International Centre
Minneapolis, MN 55402
Phone: (612)339-7461
Fax: (612)349-6556

Attorneys for Plaintiff
AGA MEDICAL CORP.

EXHIBIT A

US005108420A

United States Patent [19]

Marks

[11] Patent Number: 5,108,420

[45] Date of Patent: Apr. 28, 1992

[54] APERTURE OCCLUSION DEVICE

[75] Inventor: Lloyd A. Marks, Bryn Mawr, Pa.

[73] Assignee: Temple University, Philadelphia, Pa.

[21] Appl. No.: 649,593

[22] Filed: Feb. 1, 1991

[51] Int. Cl.[5] A61B 17/00

[52] U.S. Cl. 606/213; 606/78; 606/151; 606/157

[58] Field of Search 606/78, 151, 157, 158, 606/215, 108, 213; 128/898, 628, 686, 843, 831

[56] References Cited

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4,758,222	7/1988	McCoy	
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"The Biocompatibility of Nitinol", L. S. Castleman et al., *Biocompatibility of Clinical Implant Materials*, chap. 5, pp. 129–154.

"Nonsurgical Implantation of a Vascular Ring Prosthesis Using Thermal Shape Memory Ti/Ni Alloy (Nitinol Wire)", Yoichi Sugita et al., vol. XXXII, *Trans Am Soc Artif Intern Organs*, 1986.

"Transluminal Expandable Nitinol Coil Stent Grafting: Preliminary Report", Charles T. Dotter, M.D. et al., *Radiology* 147: 259–260, Apr. 1983.

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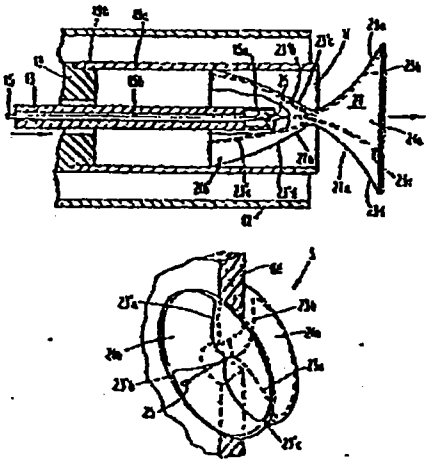
"Nonsurgical Therapy of Cardiac Disorder", Rutten-berg, *Pediatric Consult*, 5, No. 2, 1986.

Primary Examiner—Stephen C. Pellegrino
Assistant Examiner—Gary Jackson
Attorney, Agent, or Firm—Ratner & Prestia

[57] ABSTRACT

A device consisting of a wire for occluding an aperture within a body surface, such as atrial and ventricular septal defects (and the method of using such a device). The wire comprises two configurations, an elongated configuration for passage into said body through a catheter and through the aperture, and a preprogrammed configuration including occlusion-forming wire segments, one on each side of said aperture. The wire also includes means (preferably a temperature-induced shape change) for changing the wire from the elongated configuration to the preprogrammed configuration in the body.

14 Claims, 3 Drawing Sheets



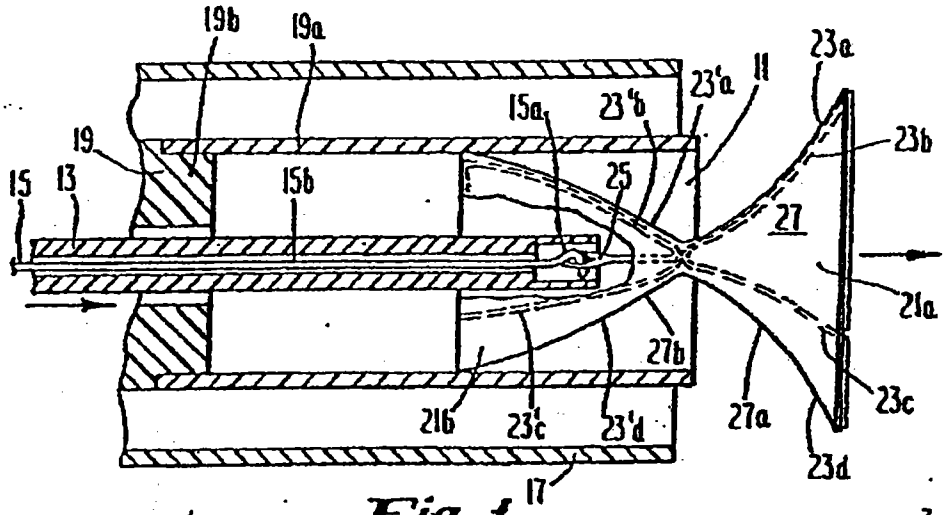


Fig. 1

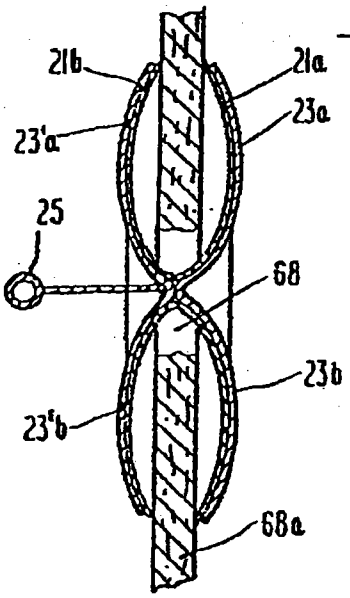


Fig. 5

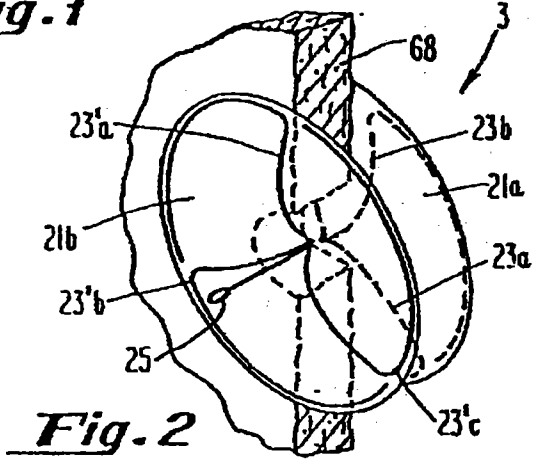


Fig. 2

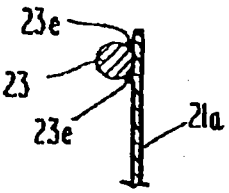


Fig. 4

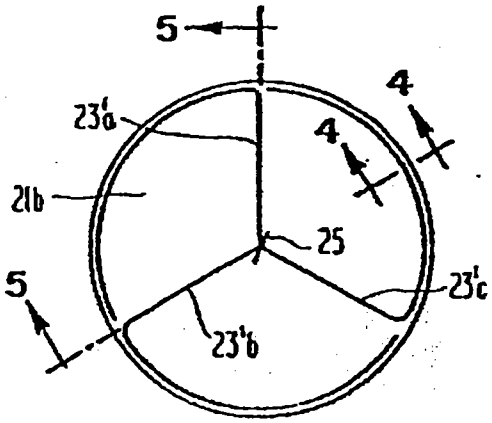


Fig. 3

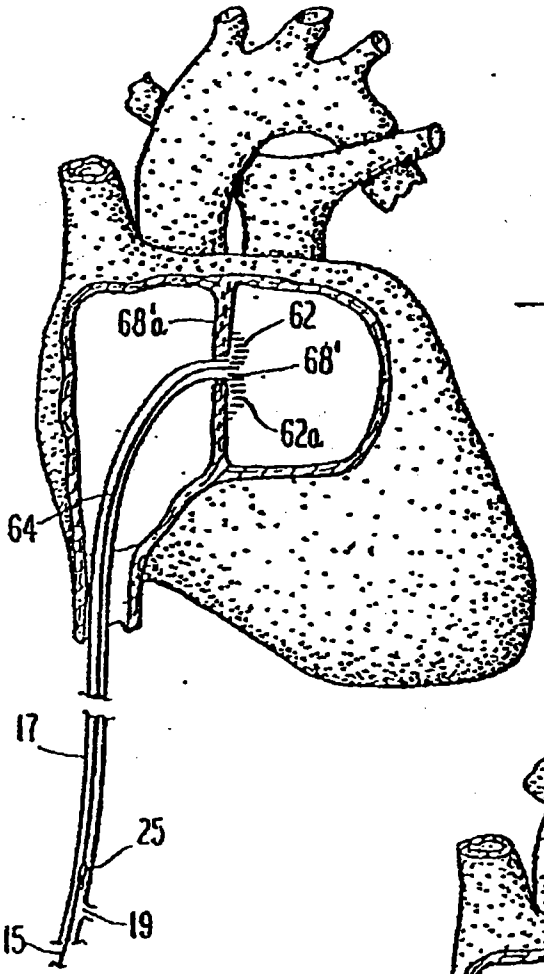


Fig. 6

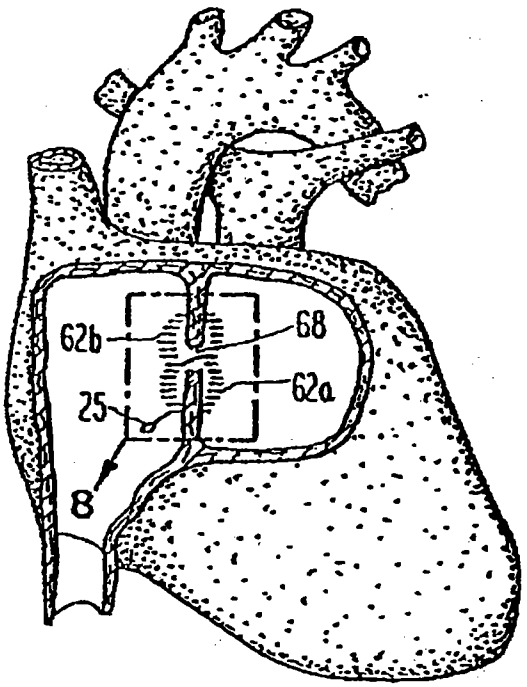


Fig. 7

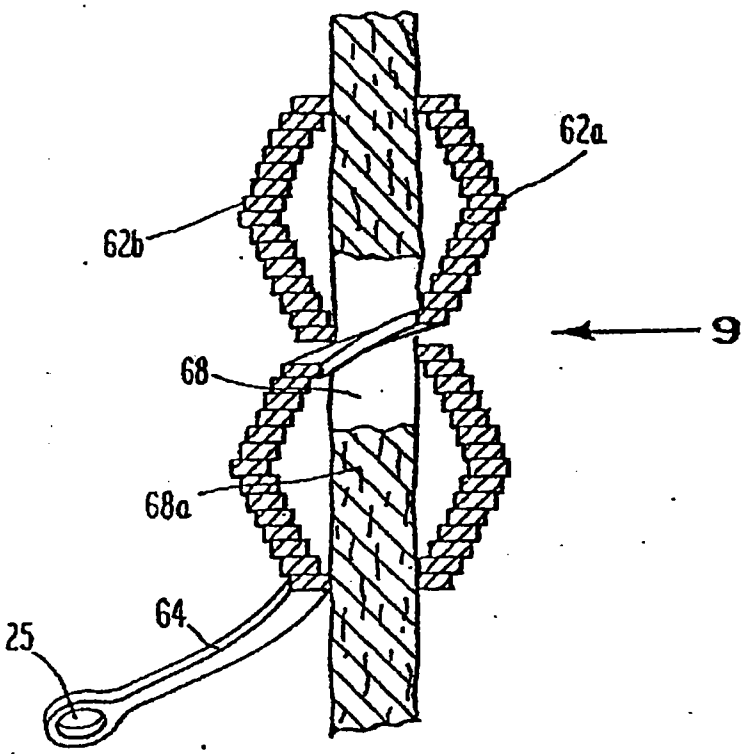


Fig. 8

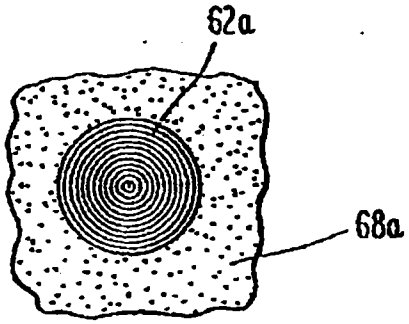


Fig. 9

APERTURE OCCLUSION DEVICE

FIELD OF THE INVENTION

The invention relates to devices and methods used to occlude (i.e. block blood flow through) an aperture within a body surface; specifically, it relates to devices and methods to occlude cardiovascular septal defects.

BACKGROUND OF THE INVENTION

It is often necessary to occlude a defect or an aperture within a body surface, such as a wall or membrane separating cavities within the body. A typical example is a congenital heart lesion called an atrial septal defect. This is a hole, between the two upper chambers of the heart, which must be closed.

King et al., U.S. Pat. No. 3,874,388, and Blake, U.S. Pat. No. 4,007,743 disclose a stainless steel apparatus for closing a shunt in the vascular system. The dual umbrella apparatus has six ribs which retain the umbrella in an open position. The King et al. apparatus has "barbs" at the ends of the ribs anchor onto the tissue surrounding the shunt. Alternatively, the barbs on the ribs of one umbrella may insert into holes on the ribs of the second umbrella, see FIG. 15A. The Blake apparatus has pivotally mounted struts which provide a flat surface to which a disk may be secured.

In "A New Percutaneous Vena Cava Filter", Cragg et al. disclose a filter composed of nitinol which when inserted into the inferior vena cava, traps emboli and clots. In the process of placing the filter, there is the threat of dislodging thrombi when the catheter or guide wire is advanced too far.

Lock et al., *In Circulation*, disclose a spring-loaded clamshell occluder of several sizes. The tension in the arms is manually controlled during delivery such that the arms of the distal umbrella, the one inserted first, are everted during placement, creating a cone.

The Rashkind occluder has two polyurethane foam disks mounted on surgical steel wire assemblies. The occluder is used to seal off the ductus arteriosus and is disclosed in *Circulation*, Vol. 75., page 583, *American Journal of Cardiology*, Vol. 64, page 218, and *Circulation*, Vol. 77, page 1068.

Devices currently used to occlude septal defects, including those indicated above, have been known to dislodge and embolize.

BRIEF DESCRIPTION OF THE INVENTION

The present invention comprises an aperture occlusion device which includes a wire having two configurations, an elongated configuration for passage through a catheter and through the aperture, and a second, preprogrammed, configuration. In the second configuration, two occlusion-forming wire segments oppose one another. These are adapted to be deployed on each side of the aperture to be occluded. A means for changing the wire from the elongated configuration to the preprogrammed configuration inside the body is further included. Typically, this may consist of a thermally responsive wire composition, the wire being preprogrammed so that at a certain temperature (body temperature for example), the wire, which is normally straight at other temperatures assumes a different ("preprogrammed") shape or configuration. Each occlusion-forming wire segment is adapted to press toward the opposing segment, thereby closing or occluding the aperture. Apertures or openings in other walls or membranes within the body or abnormally patent blood vessels may be similarly occluded.

In one embodiment, the occlusion-forming wire segments may comprise essentially flat helices, urged toward one another. In another embodiment, the wire may further include two foldable membranes, one associated with each occlusion-forming wire segment. The membranes are folded for transport through the catheter along with the wire. Upon conversion of the wire to its preprogrammed configuration, the membranes unfold onto a frame produced by the occlusion-forming wire segments, one on each side of the aperture.

Also included in the invention is a method for occluding an aperture by positioning a catheter at the distal side of the aperture and deploying a wire therethrough in an elongated configuration, (with the aid of a means for holding the wire) to the distal side of the aperture. Upon exiting the catheter, the wire converts to a preprogrammed configuration including an occlusion-forming wire segment on the distal side of the aperture. Upon continued deployment in the elongated configuration, the wire is permitted to assume the preprogrammed configuration including an opposing occlusion-forming wire segment on the proximal side of the aperture, with the two segments pressing toward one another. The wire is then disengaged from the means for holding the wire.

BRIEF DESCRIPTION OF THE FIGURES

FIG. 1 is a schematic cross-sectional view, during deployment, of one embodiment of the aperture occlusion device of the claimed invention;

FIG. 2 is a perspective view of another aperture occlusion device of the present invention in a fully deployed configuration;

FIG. 3 is planar view of the device shown in FIG. 2;

FIG. 4 is an enlarged cross-sectional view, in the plane 4—4 of FIG. 3;

FIG. 5 is a cross-sectional view, in plane 5—5, of the fully deployed aperture occlusion device shown in FIG. 3;

FIG. 6 is a perspective view of a heart, partially in cross-section, schematically showing an atrial septal defect and an occlusion device of the present invention partially deployed;

FIG. 7 is similar to FIG. 6, with the occlusion device fully deployed;

FIG. 8 is an enlarged cross-sectional view of the deployed aperture occlusion device shown in FIG. 7;

FIG. 9 is a planar view of the aperture occlusion device of FIG. 8.

DETAILED DESCRIPTION OF THE INVENTION

The invention includes devices and methods for occluding apertures in body surfaces, such as walls or membranes; the devices are adapted to be passed into the body through a catheter and through the aperture. Such apertures are openings, often congenital defects, connecting two cavities of the body. Fallopian tubes may also be occluded by using the devices and methods of the claimed invention. Cardiac septal defects are the type of apertures for which the preferred embodiments of the invention are designed. For example, the devices and methods of the present invention may be used to occlude a ventricular septal defect or an unwanted

vascular communication such as a patent ductus arteriosus.

An essential part of the present invention is a wire having two configurations, an elongated configuration or folded configuration for passage into the body through a catheter and through the aperture, and a preprogrammed configuration including occlusion-forming wire segments one on each side of the aperture. This wire also includes a means for causing it to change from the elongated configuration to the preprogrammed configuration inside the body. The device may also be combined with a catheter means for introducing the wire into the body. The catheter includes means for holding the wire, such as a release wire, while it is in the catheter and before it has been stimulated to convert to the preprogrammed configuration.

Preferably the wire is composed of a shape memory retentive material, such as nitinol, which causes the wire to change configurations, in response to a temperature change and which enables the wire to be activated at body temperature (having previously been at a different temperature) to assume a preprogrammed configuration. Spring steel may also serve this purpose. Furthermore, the wire must be biocompatible, and may be coated with Teflon, fibrin or endothelial cells, for example.

The occlusion forming wires may be associated with a foldable membrane, either by being embedded in the membrane or secured (by glue, stitches, staples or the like) to the surface thereof. In this embodiment, the membrane is transportable through a catheter in a folded configuration along with the wire. The occlusion-forming wires are adapted, upon converting to preprogrammed configuration, to unfold the membranes and to form a frame to support the membranes as domed or umbrella-shaped members on each side of the aperture. In another embodiment, the occlusion-forming wire is not attached to a membrane, and forms coiled helices, one on either side of the defect and urged toward each other.

Referring to FIG. 1, there is shown a partially deployed stage of one aperture occlusion device. As would be used for the occlusion of a septal defect, sheath 17 (a large catheter), after entering the body in a conventional manner, such as through a femoral vein, enters the heart via the inferior vena cava and is positioned on the distal side of an atrial septal defect in the body of the left atrium.

Release wire 15, including shaft 15*b* and knuckle 15*a*, device engaging catheter 13 and aperture occlusion device 27, all disposed within deployment catheter 19, are prepared as a unit prior to deployment through sheath 17 and introduced into the body either along with or later through sheath 17.

Aperture occlusion device 27 is composed of two biocompatible membranes 21*a* and 21*b*, each comprised of a thin polyurethane membrane film, for example. Preprogrammed shape memory retentive, wire ribs 23 and 23' are secured (and may be threaded, sewn or sandwiched) to each biocompatible membrane 21*a* and 21*b*. Eye 25, attached to wire ribs 23 and 23', extends from the center of aperture occlusion device 27 and engages knuckle 15*a* of release wire 15. One half of aperture occlusion device 27*b* is seen in the folded state; upon release from deployment catheter 19 and contact with body temperature, the membrane expands between the ribs, as shown by device half 27*a* with associated ribs 23. In FIG. 1, four wire ribs, 23*a–d* and 23'*a–d*, on each half of device 27, unfold, i.e. are converted from their elongated configuration to a second preprogrammed configuration, such as by a thermally stimulated shape change to a preprogrammed configuration, which urges the wire ribs outwardly, to expand and release. For this purpose, ribs 23*a–d* and 23'*a–d* are composed of a thermally responsive shape, shape memory retentive material, such as nitinol.

For transport to the site of deployment, the unit including release wire 15, device engaging catheter 13 and aperture occlusion device 27 are channeled into pod 11 of deployment catheter 19. Deployment catheter 19 includes an inner plastic portion 19*b* integrally connected to outer metal portion 19*a*. Release wire 15, device engaging catheter 13 and aperture occlusion device 27 are retained together and folded in deployment catheter 19. In practice, device 27 may be deployed without the use of deployment catheter 19, so long as sheath 17 is in a cold environment thus prohibiting device 27 from forming the preprogrammed shape.

In use, the assembly including release wire 15, device engaging catheter 13, aperture occlusion device 27 and deployment catheter 19 are passed through sheath 17 until the distal half of device 27 is disposed on the distal side of the septal defect (i.e. "aperture") to be occluded. Device engaging catheter 13, release wire 15, and aperture occlusion device 27 are maintained in place on the distal side of the defect while sheath 17 is retracted back through the defect to the proximal side thereof. Device engaging catheter 13 and release wire 15 are advanced freeing 27*a* to expand to preprogrammed shape. This enables a thermally stimulated shape change to the preprogrammed deployed configuration of ribs 23*a–d*. One-half of aperture occlusion device, 27*a*, is thus deployed on the distal side of the septal defect.

Coincident with the pull-back movement of deployment catheter 19 either in the preceding step or in the following step, sheath 17 is also retracted away from the aperture to be occluded.

Aperture occlusion device 27 is then pulled taut against the defect such that four wire ribs 23*a–d* expand and contact the heart tissue around the defect. Optionally, sheath 17 is then pulled back further away from the proximal side of the defect (if that had not been done earlier), and deployment catheter 19 is retracted leaving device engaging catheter 13, release wire 15, and aperture occlusion device 27 in place and thus exposing aperture occlusion device half 27*b* on the proximal side of the defect, at which point the second half 27*b* of device 27 is deployed.

Once aperture occlusion device 27 is fully deployed, as seen in FIGS. 2-5, knuckle 15*a* is disengaged from eye 25 of aperture occlusion device 27, by retracting catheter 13 slightly from eye 25. The assembly including deployment catheter 19, device engaging catheter 13 and release wire 15 are then retracted from sheath 17. Finally, sheath 17 is also retracted from the body.

FIG. 2 depicts a perspective view of an aperture occlusion device, with 3 ribs, like that seen in FIG. 1, but fully deployed to occlude a defect or aperture 68 in wall 68*a*. Membranes 21*a* and 21*b* are supported by wire ribs 23*a–c* and 23'*a–c* respectively, which urge the membranes toward each other and connect the membranes with eye 25.

As seen in FIG. 3, membrane 21*a* is attached to three wire ribs 23*a*, *b* and *c* extending circumferentially then curving and radially extending to the center of membrane 21*a*. Ribs 23*a–c* attach at the center of membrane

21a and connect the pair to each other and to eye 25 which attaches to a release wire, not shown. Ribs 23a–c, upon thermal triggering of the memory retentive properties of the rib material (preferably nitinol), support and maintain the shape of membrane 21a. Membrane 21b is similarly retained by ribs 23'a–c.

FIG. 4 is a cross-section through plane 4—4 of FIG. 3. As depicted therein, membrane 21a is secured to rib 23a by glue 23e. Stitches, staples or the like may also be used to affix membrane 21a to rib 23a. Other configurations of ribs 23a, b, c may also be used.

FIG. 5 illustrates a cross-section along plane 5—5 of the aperture occlusion device of FIG. 3. Membranes 21a and 21b occlude aperture 68 in wall 68a, and are supported by wire ribs, 23a, b and 23'a, b, which urge the membranes toward each other and connect the membranes with eye 25.

FIG. 6 depicts septal defect 68' with a double helix occlusion device 62 partially deployed. Device 62 is introduced as a straight wire 64 through the assembly including, device engaging catheter 13 (like that shown in FIG. 1, but not shown in FIG. 6 due to limited space available), release wire 15 and sheath 17. Sheath 17 is diametrically larger than device engaging catheter 13 to allow passage of device engaging catheter 13 therethrough. As with the assembly shown in and described with respect to FIG. 1, the assembly of release wire 15, device engaging catheter 13, wire 64 and sheath 17 are introduced through a large vein to and through the defect to be occluded. Sheath 17 optionally may be stopped short of defect 68' and may be withdrawn with device engaging catheter 13, as described, or independently of catheter 13.

Helix 62a is formed on the distal side of defect 68', preferably by the coiling of wire 64, nitinol for example, in response to a temperature change, upon body temperature contact or by retraction of spring steel into its "relaxed" (preprogrammed) configuration. A plurality of coils of progressively smaller diameter are formed, finally contacting the periphery of atrial wall 68a' surrounding defect 68' on the distal side thereof; each such coil of wire 64 contacts the previously formed coil above and below defect 68', such that helix 62a is deployed from the outside in, (relative to defect 68), until helix 62a is formed (as seen in FIG. 6).

The aperture occlusion device of FIG. 6 after deployment into the left atrium is seen in FIG. 9. The concentric circles are the result of the coiling of wire 64 (in this case from a very small starting circumference out) and also contacting the previously formed coil above and below defect 68', this time on the proximal side thereof.

After deploying helix 62a on the distal side of defect 68, sheath 17, device engaging catheter 13, release wire 15, and wire 64 are withdrawn equally and together to bring helix 62a into firm contact with the septal surface. As tension is maintained on wire 64 via release wire 15, sheath 17 is withdrawn over wire 64 and release wire 15, thereby exposing a length of wire 64 on the proximal side of the defect. Tension on wire 64 is then slowly reduced by advancing release wire 15 and sheath 17 equally and together. Wire 64 begins coiling at or near septal surface below defect 68. By progressively reducing tension on wire 64 (by repetitively withdrawing sheath 17 over release wire 15 and advancing sheath 17 and release wire 15 equally and together), successive coils are formed, each moving outward beyond the previously formed coil. Thus, helix 62b is formed from the inside out, until helix 62b is fully deployed as seen in FIGS. 7 and 8. Eye 25 is then disengaged from the release wire 15 (not shown), and the remaining apparatus is removed from the body as described with respect to FIG. 1.

In those embodiments dependent upon a thermally responsive change (such as with nitinol) as the means for effecting device deployment, it is desirable prior to deployment to continuously infuse a biocompatible fluid (such as normal saline) which is substantially below body temperature (for example at room temperature) through side port 19 of sheath 17 to maintain a thermal environment within sheath 17, that is below the transition temperature of the thermally responsive wire 64. This assures that wire 64 will not assume its programmed shape until it exits sheath 17.

Furthermore, the programmed deployed configuration of the double helix coil (in the embodiment of FIGS. 6–9) may preferably include shaping to urge the outermost coils of helices 62a and 62b toward the septal surface (and one another) to provide an increased frictional force between the helices and their respective septal surfaces.

By way of general description of the method of this invention, the device of the present invention may be used in a method of occluding an aperture within a body surface. A catheter, which can accommodate a wire in an elongated or folded configuration (optionally with an associated membrane), is introduced through a body member such as a femoral vein, deployed, for example, into the heart through the inferior vena cava and manipulated into position on the distal side of the aperture where the wire assumes its preprogrammed configuration including an occlusion-forming wire segment urged toward the aperture on the distal side of the septal defect. Withdrawing the catheter partially over the wire allows a substantial length of the wire to be exposed on the near side of the defect. Upon further deployment, the wire assumes a preprogrammed configuration including an occlusion-forming wire segment urged toward the aperture on the proximal side of the aperture. The wire is then disengaged from the means for holding it.

The device and method of this invention are believed to be particularly well adapted to occlude both atrial and ventricular septal defects, as well as other cardiovascular openings, such as a patent ductus arteriosus. The device (modified for tubal rather than aperture occlusion) is also well suited for use in occluding fallopian tubes.

In the embodiments disclosed, the finished structure comprises two connected occlusion-forming wire segments, disposed on opposite sides of an aperture, each formed of a wire resulting in helices, or domed members (with membranes attached to a wire frame), urged toward one another.

While this invention has been disclosed with reference to specific embodiments, it is apparent that other embodiments and equivalent variations of this invention may be devised by those skilled in the art without departing from the true spirit and scope of this invention. The appended claims are intended to be construed to include all such embodiments and equivalent variations.

What is claimed is:

1. A device adapted to occlude an aperture within a body surface, and adapted to be passed into said body, through a catheter and through said aperture, said device comprising a wire having two configurations, an elongated configuration for passage through said cathe-

ter and through said aperture, and a preprogrammed configuration which includes occlusion-forming wire segments one on each side of said aperture urged toward one another and means for causing said wire to change from said elongated configuration to said preprogrammed configuration inside said body, said means being a temperature responsive material of construction of said wire, by which said wire is activated at body temperature, to assume said preprogrammed configuration.

2. A device of claim 1 wherein said wire is combined with a catheter means for introducing said wire into said body, said catheter means also includes means for holding said wire, while it is in said catheter, at a temperature at which said wire does not tend to assume said preprogrammed configuration.

3. A device of claim 1 wherein said occlusion-forming segments each comprise helical coils urged toward one another.

4. A device of claim 1 wherein said wire further includes two foldable membranes, one associated with said first occlusion-forming wire segment and the other associated with said second occlusion-forming wire segment, said membranes in folded configuration being transportable through a catheter along with said wire, said wire adapted upon converting from said elongated configuration to said preprogrammed configuration to unfold said membranes and to form a frame supporting said membranes as essentially planar members, one disposed on each side of said aperture, and urged toward one another, wherein said means for causing a change in configuration is a thermally responsive material of construction.

5. A device according to claim 4 wherein said wire is secured to said membranes of said occlusion-forming wire segments.

6. A device according to claim 1, wherein said wire consists of nitinol.

7. A device according to claim 1, wherein said wire is biocompatible.

8. A device according to claim 1, wherein said wire is coated to enhance biocompatibility.

9. A device adapted to occlude an aperture within a body surface, and adapted to be passed into said body, through a catheter and through said aperture, said device comprising a wire having two configurations, an elongated configuration for passage through said catheter and through said aperture, and a preprogrammed configuration which includes occlusion-forming wire segments one on each side of said aperture, and means for causing said wire to change from said elongated configuration to said preprogrammed configuration inside said body, wherein said occlusion forming segments each comprise helical coils urged toward one another.

10. A device according to claim 9, wherein said wire consists of spring steel.

11. A method for occluding an aperture within a body surface by positioning the end of a catheter at the distal side of the aperture, deploying a wire of temperature responsive material of construction in an elongated configuration through said catheter to the distal side of said aperture with the aid of a means for holding said wire, permitting the wire exposed thereby to assume a preprogrammed configuration, including an occlusion-forming wire segment on the distal side of said aperture, and urged toward said aperture, withdrawing the end of said catheter through said aperture and deploying an additional length of said wire in an elongated configuration to be exposed on the proximal side of said aperture, whereupon said continued deployment, said wire is permitted to assume a preprogrammed configuration, including an opposing occlusion-forming wire segment urged toward said aperture on the proximal side of the aperture, and disengaging the wire from the means for holding said wire.

12. A method as recited in claim 11, wherein said defect is a atrial septal defect.

13. A method as recited in claim 11, wherein said defect is a ventricular septal defect.

14. A method as recited in claim 11, wherein said defect is a patent ductus arteriosus.

* * * * *

EXHIBIT B

DEC 10 '98 14:50 FR HALE AND DORR LLP 526 5000 TO 71111#106586*132 P.02

JS 44
(Rev. 12/96)

CIVIL COVER SHEET

The JS-44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

PLAINTIFFS

Nitinol Medical Technologies, Inc. and Lloyd A. Marks

(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF Suffolk
(EXCEPT IN U.S. PLAINTIFF CASES)

DEFENDANTS

AGA Medical Corporation

COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT _____
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

(c) ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER)
Hale and Dorr LLP
60 State Street
Boston, MA 02109

ATTORNEYS (IF KNOWN)

I. BASIS OF JURISDICTION (PLACE AN "X" IN ONE BOX ONLY)

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (PLACE AN "X" IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated or Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated and Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

V. ORIGIN (PLACE AN "X" IN ONE BOX ONLY)

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. NATURE OF SUIT (PLACE AN "X" IN ONE BOX ONLY)

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

PERSONAL INJURY
- ☐ 362 Personal Injury – Med. Malpractice
- ☐ 365 Personal Injury – Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 440 Other Civil Rights

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence
- HABEAS CORPUS:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

FORFEITURE/PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs.
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt. Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc Security Act

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☒ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS – Third Party 26 USC 7609

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce/ICC Rates/etc.
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900 Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes
- ☐ 890 Other Statutory Actions

VII. CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE BRIEF STATEMENT OF CAUSE. DO NOT CITE JURISDICTIONAL STATUTES UNLESS DIVERSITY.)

Action for patent infringement under 35 U.S.C. Sec. 271

VIII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION ☐ UNDER F.R.C.P. 23

DEMAND $

CHECK YES only if demanded in complaint
JURY DEMAND: ☒ Yes ☐ No

IX. RELATED CASE(S) IF ANY (See instructions):

JUDGE _____ DOCKET NUMBER _____

DATE 12/10/98

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG JUDGE _____

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

1. TITLE OF CASE (NAME OF FIRST PARTY ON EACH SIDE ONLY) Nitinol Medical Technologies, Inc. v. AGA Medical Corporation

2. CATEGORY IN WHICH THE CASE BELONGS BASED UPON THE NUMBERED NATURE OF SUIT CODE LISTED ON THE CIVIL COVER SHEET. (SEE LOCAL RULE 40.1(A)(1)).

___	I.	160, 410, 470, R.23, REGARDLESS OF NATURE OF SUIT.	
XX	II.	195, 368, 400, 440, 441-444, 540, 550, 555, 625, 710, 720, 730, 740, 790, 791, 820*, 830*, 840*, 850, 890, 892-894, 895, 950.	*Also complete AO 120 or AO 121 for patent, trademark or copyright cases
___	III.	110, 120, 130, 140, 151, 190, 210, 230, 240, 245, 290, 310, 315, 320, 330, 340, 345, 350, 355, 360, 362, 365, 370, 371, 380, 385, 450, 891.	
___	IV.	220, 422, 423, 430, 460, 510, 530, 610, 620, 630, 640, 650, 660, 690, 810, 861-865, 870, 871, 875, 900.	
___	V.	150, 152, 153.	

3. TITLE AND NUMBER, IF ANY, OF RELATED CASES. (SEE LOCAL RULE 40.1(E)). None

4. HAS A PRIOR ACTION BETWEEN THE SAME PARTIES AND BASED ON THE SAME CLAIM EVER BEEN FILED IN THIS COURT? YES ☐ NO ☒

5. DOES THE COMPLAINT IN THIS CASE QUESTION THE CONSTITUTIONALITY OF AN ACT OF CONGRESS AFFECTING THE PUBLIC INTEREST? (SEE 28 USC 2403) YES ☐ NO ☒
IF SO, IS THE U.S.A. OR AN OFFICER, AGENT OR EMPLOYEE OF THE U.S. A PARTY? YES ☐ NO ☐

6. IS THIS CASE REQUIRED TO BE HEARD AND DETERMINED BY A DISTRICT COURT OF THREE JUDGES PURSUANT TO TITLE 28 USC 2284? YES ☐ NO ☒

7. DO ALL PARTIES IN THIS ACTION RESIDE IN THE CENTRAL SECTION OF THE DISTRICT OF MASSACHUSETTS (WORCESTER COUNTY) - (SEE LOCAL RULE 40.1(C)). YES ☐ NO ☒
OR IN THE WESTERN SECTION (BERKSHIRE, FRANKLIN, HAMPDEN OR HAMPSHIRE COUNTIES)? - (SEE LOCAL RULE 40.1(D)). YES ☐ NO ☒

8. DO ALL OF THE PARTIES RESIDING IN MASSACHUSETTS RESIDE IN THE CENTRAL AND/OR WESTERN SECTIONS OF THE DISTRICT? YES ☐ NO ☒
(a) IF YES, IN WHICH SECTION DOES THE PLAINTIFF RESIDE? _____

9. IN WHICH SECTION DO "ONLY" PARTIES RESIDING IN MASSACHUSETTS RESIDE? Eastern

10. IF ANY OF THE PARTIES ARE THE UNITED STATES, COMMONWEALTH OF MASSACHUSETTS, OR ANY GOVERNMENTAL AGENCY OF THE U.S.A. OR THE COMMONWEALTH, DO ALL OTHER PARTIES RESIDE IN THE CENTRAL SECTION: YES ☐ NO ☐ OR WESTERN SECTION: YES ☐ NO ☐

(PLEASE TYPE OR PRINT)

ATTORNEY'S NAME William F. Lee, Esq.
ADDRESS Hale and Dorr LLP 60 State Street Boston, MA 02109
TELEPHONE NO. (617) 526-6000

(Category Form - 3/97)

AO 440 (Rev. 10/93) Summons in a Civil Action

United States District Court

DISTRICT OF MASSACHUSETTS

NITINOL MEDICAL TECHNOLOGIES, INC.
and
LLOYD A. MARKS

V.

AGA MEDICAL CORPORATION

SUMMONS IN A CIVIL ACTION

CASE NUMBER:

98CV12506NG

TO: (Name and Address of Defendant)
AGA Medical Corporation
682 Mendelssohn Avenue
Golden Valley, MN 55427

YOU ARE HEREBY SUMMONED and required to file with the Clerk of this Court and serve upon

PLAINTIFF'S ATTORNEY (name and address)

William F. Lee, Esq.
Hale and Dorr LLP
60 State Street
Boston, MA 02109

an answer to the complaint which is herewith served upon you, within 20 (twenty) days after service of this summons upon you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint.

CLERK

DATE

BY DEPUTY CLERK

DEC 10 '98 14:50 FR HALE AND DORR LLP 526 5000 TO 71111#106586*132 P.05

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

NITINOL MEDICAL TECHNOLOGIES, Inc. and LLYOD A. MARKS,

Plaintiffs,

v.

AGA MEDICAL CORPORATION,

Defendant.

Civil Action No. _____

JURY TRIAL DEMANDED

98CV12506NG

COMPLAINT FOR PATENT INFRINGEMENT

NATURE OF ACTION

This is an action under the patent laws of the United States, Title 35 of the United States Code, for infringement of United States Patent No. 5,108,420.

THE PARTIES

1. Plaintiff Nitinol Medical Technologies, Inc. ("Nitinol") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business in Boston, Massachusetts.

2. Plaintiff Lloyd A. Marks ("Marks") is a resident of Westfield, New Jersey.

3. Defendant AGA Medical Corporation ("AGA Medical"), is a Minnesota corporation, having its principal place of business in Golden Valley, Minnesota.

JURISDICTION AND VENUE

4. This is an action for patent infringement arising under Title 35 of the United States Code. Accordingly, this Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1338(a).

5. Venue is proper in this jurisdiction pursuant to 28 U.S.C. §§ 1391(b), 1391(c) and/or 1400(b).

ACTS GIVING RISE TO THE COMPLAINT

6. Plaintiff Marks is the inventor and owner by reassignment of United States Patent No. 5,108,420 (the "'420 patent"), entitled "Aperture Occlusion Device." A copy of the '420 patent is attached as Exhibit A.

7. Plaintiff Nitinol is the exclusive worldwide licensee of the right to make, use and sell products embodying the '420 patent and/or manufactured according to the methods of the '420 patent.

8. Defendant AGA Medical manufactures, offers for sale or sells medical devices which infringe one or more claim of the '420 patent.

9. Defendant AGA Medical is currently making, using or selling, and will, unless enjoined, continue to make, use or sell, medical devices infringing one or more claim of the '420 patent.

10. On information and belief, Defendant AGA Medical's acts of infringement are willful and deliberate.

WHEREFORE, plaintiffs Nitinol and Marks request that judgment be entered in their favor, and that they be granted the following relief:

i. A judgment that AGA Medical has infringed the '420 patent, and that such infringement has been willful;

ii. A permanent injunction restraining AGA Medical, its officers, agents, servants, employees and those acting in concert with it, from infringing the '420 patent;

iii. An award of damages sufficient to compensate Nitinol and Marks for the infringement complained of herein;

iv. An award of enhanced damages in the amount of three times the damages found or assessed, attorneys' fees, disbursements and costs of suit; and

v. Such other and further relief as the Court deems just and proper.

PLAINTIFFS HEREBY DEMAND TRIAL BY JURY.

Dated: December 10, 1998

NITINOL MEDICAL TECHNOLOGIES, INC. and LLOYD A. MARKS

By their attorneys,

William F. Lee (BBO #291960)
William G. McElwain (BBO #332510)
Dominic E. Massa (BBO #564694)
Hale and Dorr LLP
60 State Street
Boston, Massachusetts 02109
(617) 526-6000

US005108420A

United States Patent [19]

Marks

[11] Patent Number: 5,108,420

[45] Date of Patent: Apr. 28, 1992

[54] APERTURE OCCLUSION DEVICE

[75] Inventor: Lloyd A. Marks, Bryn Mawr, Pa.

[73] Assignee: Temple University, Philadelphia, Pa.

[21] Appl. No.: 649,593

[22] Filed: Feb. 1, 1991

[51] Int. Cl.[5] A61B 17/00

[52] U.S. Cl. 606/213; 606/78; 606/151; 606/157

[58] Field of Search 606/78, 151, 157, 158, 606/215, 108, 213; 128/898, 628, 686, 843, 831

[56] References Cited

U.S. PATENT DOCUMENTS

3,868,956	3/1975	Alfidi et al.	
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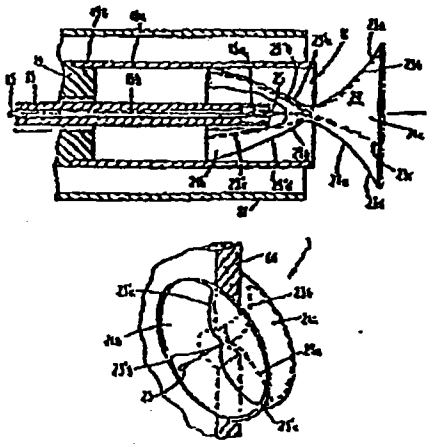
Primary Examiner—Stephen C. Pellegrino
Assistant Examiner—Gary Jackson
Attorney, Agent, or Firm—Ratner & Prestia

[57] ABSTRACT

A device consisting of a wire for occluding an aperture within a body surface, such as atrial and ventricular septal defects (and the method of using such a device). The wire comprises two configurations, an elongated configuration for passage into said body through a catheter and through the aperture, and a preprogrammed configuration including occlusion-forming wire segments, one on each side of said apertore. The wire also includes means (preferably, a temperature-induced shape change) for changing the wire from the elongated configuration to the preprogrammed configuration in the body.

14 Claims, 3 Drawing Sheets



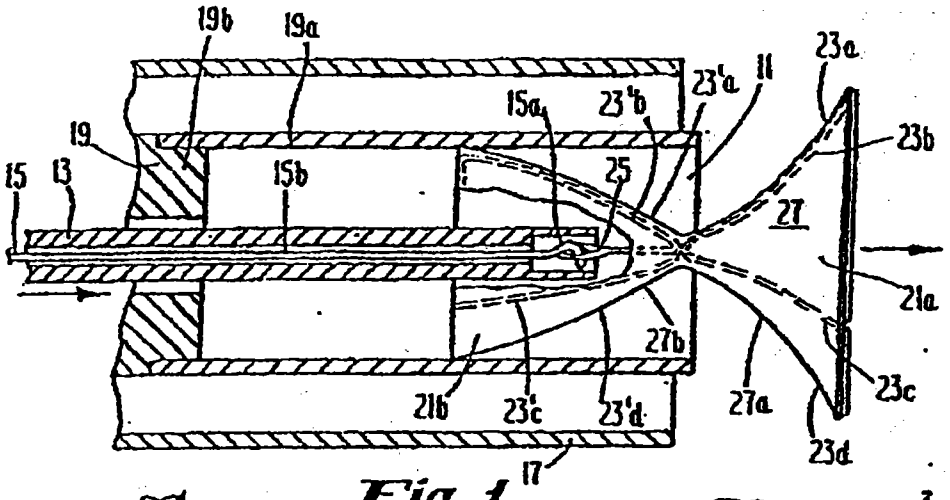


Fig. 1

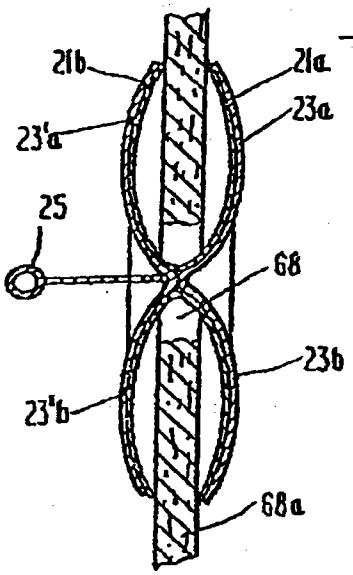


Fig. 5

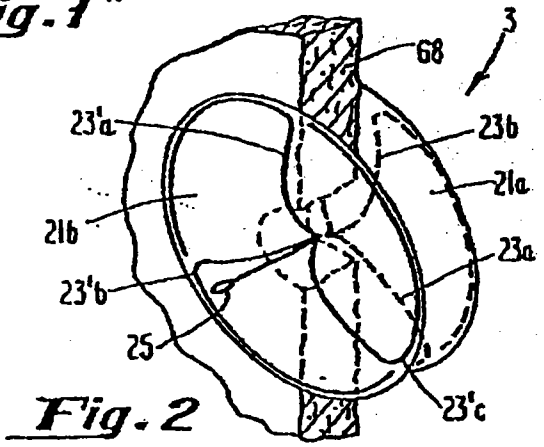


Fig. 2

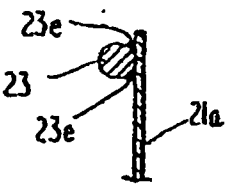


Fig. 4

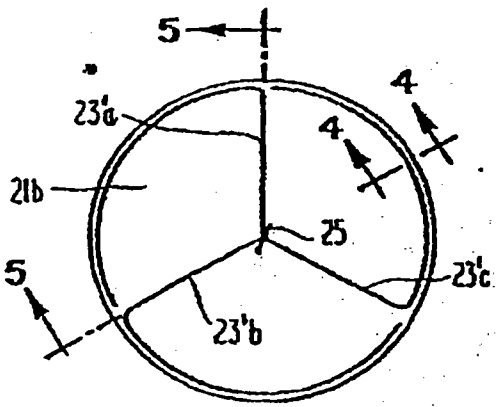


Fig. 3

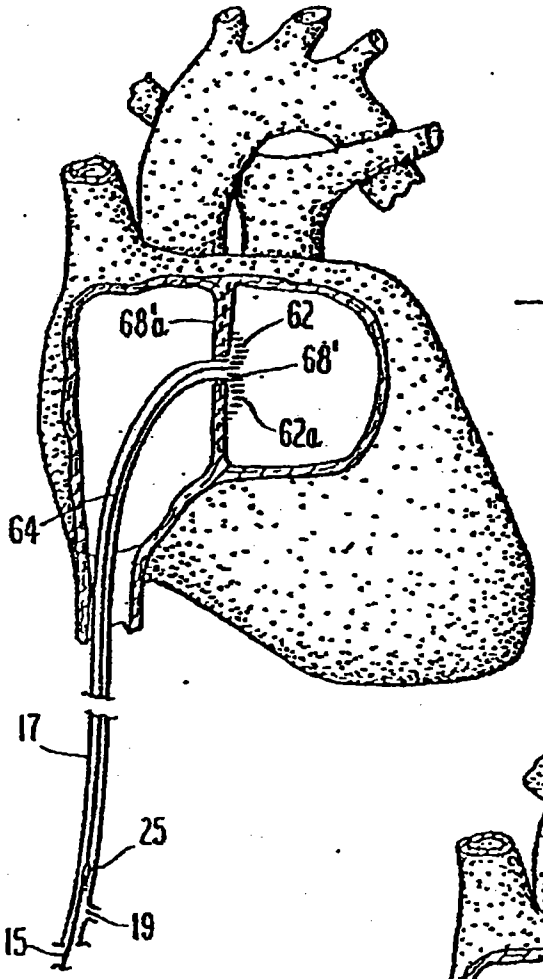


Fig. 6

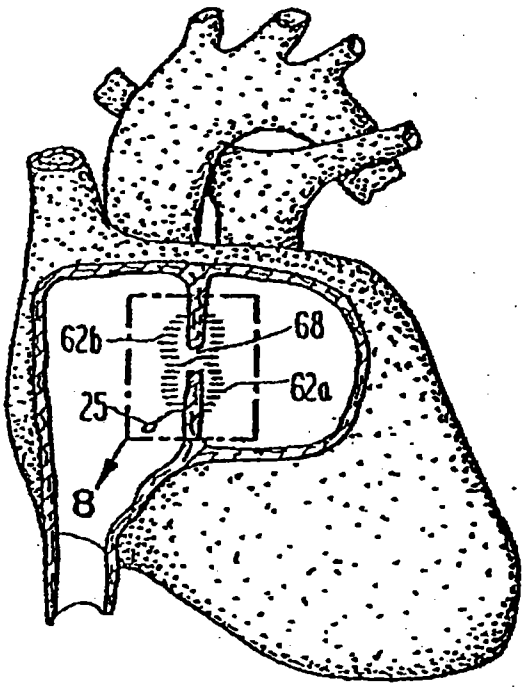


Fig. 7

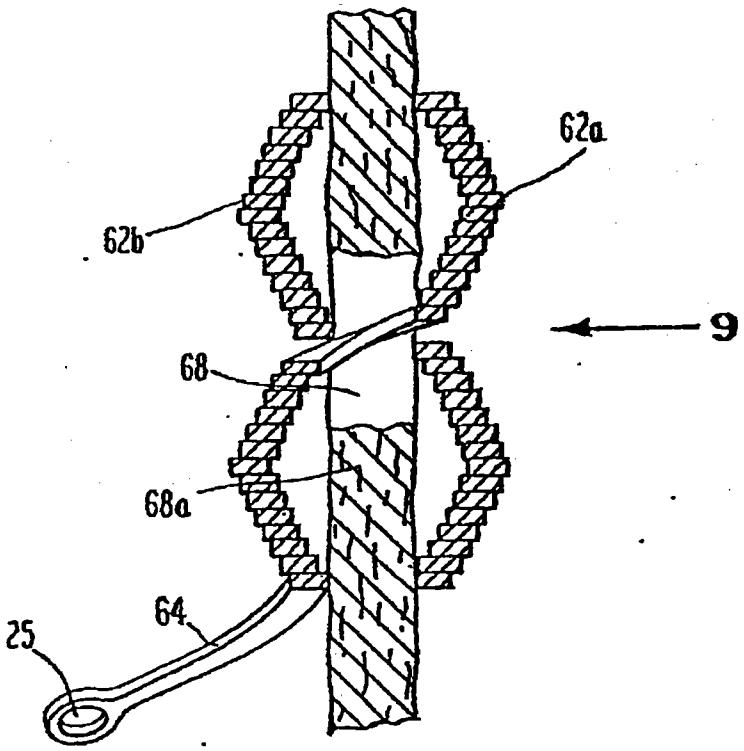


Fig. 8

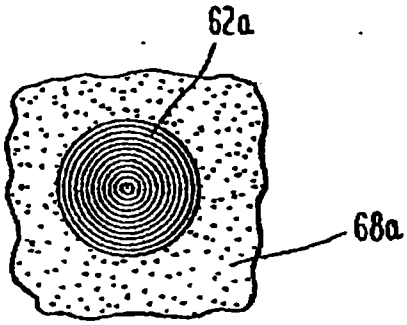


Fig. 9

APERTURE OCCLUSION DEVICE

FIELD OF THE INVENTION

The invention relates to devices and methods used to occlude (i.e. block blood flow through) an aperture within a body surface; specifically, it relates to devices and methods to occlude cardiovascular septal defects.

BACKGROUND OF THE INVENTION

It is often necessary to occlude a defect or an aperture within a body surface, such as a wall or membrane separating cavities within the body. A typical example is a congenital heart lesion called an atrial septal defect. This is a hole, between the two upper chambers of the heart, which must be closed.

King et al., U.S. Pat. No. 3,874,388, and Blake, U.S. Pat. No. 4,007,743 disclose a stainless steel apparatus for closing a shunt in the vascular system. The dual umbrella apparatus has six ribs which retain the umbrella in an open position. The King et al. apparatus has "barbs" at the ends of the ribs anchor onto the tissue surrounding the shunt. Alternatively, the barbs on the ribs of one umbrella may insert into holes on the ribs of the second umbrella, see FIG. 15A. The Blake apparatus has pivotally mounted struts which provide a flat surface to which a disk may be secured.

In "A New Percutaneous Vena Cava Filter", Cragg et al. disclose a filter composed of nitinol which when inserted into the inferior vena cava, traps emboli and clots. In the process of placing the filter, there is the threat of dislodging thrombi when the catheter or guide wire is advanced too far.

Lock et al., in *Circulation*, disclose a spring-loaded clamshell occluder of several sizes. The tension in the arms is manually controlled during delivery such that the arms of the distal umbrella, the one inserted first, are everted during placement, creating a cone.

The Rashkind occluder has two polyurethane foam disks mounted on surgical steel wire assemblies. The occluder is used to seal off the ductus arteriosus and is disclosed in *Circulation*, Vol. 75., page 583, *American Journal of Cardiology*, Vol. 64, page 218, and *Circulation*, Vol. 77, page 1068.

Devices currently used to occlude septal defects, including those indicated above, have been known to dislodge and embolize.

BRIEF DESCRIPTION OF THE INVENTION

The present invention comprises an aperture occlusion device which includes a wire having two configurations, an elongated configuration for passage through a catheter and through the aperture, and a second, preprogrammed, configuration. In the second configuration, two occlusion-forming wire segments oppose one another. These are adapted to be deployed on each side of the aperture to be occluded. A means for changing the wire from the elongated configuration to the preprogrammed configuration inside the body is further included. Typically, this may consist of a thermally responsive wire composition, the wire being preprogrammed so that at a certain temperature (body temperature for example), the wire, which is normally straight at other temperatures assumes a different ("preprogrammed") shape or configuration. Each occlusion-forming wire segment is adapted to press toward the opposing segment, thereby closing or occluding the aperture. Apertures or openings in other walls or membranes within the body or abnormally patent blood vessels may be similarly occluded.

In one embodiment, the occlusion-forming wire segments may comprise essentially flat helices, urged toward one another. In another embodiment, the wire may further include two foldable membranes, one associated with each occlusion-forming wire segment. The membranes are folded for transport through the catheter along with the wire. Upon conversion of the wire to its preprogrammed configuration, the membranes unfold onto a frame produced by the occlusion-forming wire segments, one on each side of the aperture.

Also included in the invention is a method for occluding an aperture by positioning a catheter at the distal side of the aperture and deploying a wire therethrough in an elongated configuration, (with the aid of a means for holding the wire) to the distal side of the aperture. Upon exiting the catheter, the wire converts to a preprogrammed configuration including an occlusion-forming wire segment on the distal side of the aperture. Upon continued deployment in the elongated configuration, the wire is permitted to assume the preprogrammed configuration including an opposing occlusion-forming wire segment on the proximal side of the aperture, with the two segments pressing toward one another. The wire is then disengaged from the means for holding the wire.

BRIEF DESCRIPTION OF THE FIGURES

FIG. 1 is a schematic cross-sectional view, during deployment, of one embodiment of the aperture occlusion device of the claimed invention;

FIG. 2 is a perspective view of another aperture occlusion device of the present invention in a fully deployed configuration;

FIG. 3 is planar view of the device shown in FIG. 2;

FIG. 4 is an enlarged cross-sectional view, in the plane 4—4 of FIG. 3;

FIG. 5 is a cross-sectional view, in plane 5—5, of the fully deployed aperture occlusion device shown in FIG. 3;

FIG. 6 is a perspective view of a heart, partially in cross-section, schematically showing an atrial septal defect and an occlusion device of the present invention partially deployed;

FIG. 7 is similar to FIG. 6, with the occlusion device fully deployed;

FIG. 8 is an enlarged cross-sectional view of the deployed aperture occlusion device shown in FIG. 7;

FIG. 9 is a planar view of the aperture occlusion device of FIG. 8.

DETAILED DESCRIPTION OF THE INVENTION

The invention includes devices and methods for occluding apertures in body surfaces, such as walls or membranes; the devices are adapted to be passed into the body through a catheter and through the aperture. Such apertures are openings, often congenital defects, connecting two cavities of the body. Fallopian tubes may also be occluded by using the devices and methods of the claimed invention. Cardiac septal defects are the type of apertures for which the preferred embodiments of the invention are designed. For example, the devices and methods of the present invention may be used to occlude a ventricular septal defect or an unwanted

vascular communication such as a patent ductus arteriosus.

An essential part of the present invention is a wire having two configurations, an elongated configuration or folded configuration for passage into the body through a catheter and through the aperture, and a preprogrammed configuration including occlusion-forming wire segments one on each side of the aperture. This wire also includes a means for causing it to change from the elongated configuration to the preprogrammed configuration inside the body. The device may also be combined with a catheter means for introducing the wire into the body. The catheter includes means for holding the wire, such as a release wire, while it is in the catheter and before it has been stimulated to convert to the preprogrammed configuration.

Preferably the wire is composed of a shape memory retentive material, such as nitinol, which causes the wire to change configurations, in response to a temperature change and which enables the wire to be activated at body temperature (having previously been at a different temperature) to assume a preprogrammed configuration. Spring steel may also serve this purpose. Furthermore, the wire must be biocompatible, and may be coated with Teflon, fibrin or endothelial cells, for example.

The occlusion forming wires may be associated with a foldable membrane, either by being embedded in the membrane or secured (by glue, stitches, staples or the like) to the surface thereof. In this embodiment, the membrane is transportable through a catheter in a folded configuration along with the wire. The occlusion-forming wires are adapted, upon converting to preprogrammed configuration, to unfold the membranes and to form a frame to support the membranes as domed or umbrella-shaped members on each side of the aperture. In another embodiment, the occlusion-forming wire is not attached to a membrane, and forms coiled helices, one on either side of the defect and urged toward each other.

Referring to FIG. 1, there is shown a partially deployed stage of one aperture occlusion device. As would be used for the occlusion of a septal defect, sheath 17 (a large catheter), after entering the body in a conventional manner, such as through a femoral vein, enters the heart via the inferior vena cava and is positioned on the distal side of an atrial septal defect in the body of the left atrium.

Release wire 15, including shaft 15*b* and knuckle 15*a*, device engaging catheter 13 and aperture occlusion device 27, all disposed within deployment catheter 19, are prepared as a unit prior to deployment through sheath 17 and introduced into the body either along with or later through sheath 17.

Aperture occlusion device 27 is composed of two biocompatible membranes 21*a* and 21*b*, each comprised of a thin polyurethane membrane film, for example. Preprogrammed shape memory retentive, wire ribs 23 and 23' are secured (and may be threaded, sewn or sandwiched) to each biocompatible membrane 21*a* and 21*b*. Eye 25, attached to wire ribs 23 and 23', extends from the center of aperture occlusion device 27 and engages knuckle 15*a* of release wire 15. One half of aperture occlusion device 27*b* is seen in the folded state; upon release from deployment catheter 19 and contact with body temperature, the membrane expands between the ribs, as shown by device half 27*a* with associated ribs 23. In FIG. 1, four wire ribs, 23*a–d* and 23'*a–d*, on each half of device 27, unfold, i.e. are converted from their elongated configuration to a second preprogrammed configuration, such as by a thermally stimulated shape change to a preprogrammed configuration, which urges the wire ribs outwardly, to expand and release. For this purpose, ribs 23*a–d* and 23'*a–d* are composed of a thermally responsive shape, shape memory retentive material, such as nitinol.

For transport to the site of deployment, the unit including release wire 15, device engaging catheter 13 and aperture occlusion device 27 are channeled into pod 11 of deployment catheter 19. Deployment catheter 19 includes an inner plastic portion 19*b* integrally connected to outer metal portion 19*a*. Release wire 15, device engaging catheter 13 and aperture occlusion device 27 are retained together and folded in deployment catheter 19. In practice, device 27 may be deployed without the use of deployment catheter 19, so long as sheath 17 is in a cold environment thus prohibiting device 27 from forming the preprogrammed shape.

In use, the assembly including release wire 15, device engaging catheter 13, aperture occlusion device 27 and deployment catheter 19 are passed through sheath 17 until the distal half of device 27 is disposed on the distal side of the septal defect (i.e. "aperture") to be occluded. Device engaging catheter 13, release wire 15, and aperture occlusion device 27 are maintained in place on the distal side of the defect while sheath 17 is retracted back through the defect to the proximal side thereof. Device engaging catheter 13 and release wire 15 are advanced freeing 27*a* to expand to preprogrammed shape. This enables a thermally stimulated shape change to the preprogrammed deployed configuration of ribs 23*a–d*. One-half of aperture occlusion device, 27*a*, is thus deployed on the distal side of the septal defect.

Coincident with the pull-back movement of deployment catheter 19 either in the preceding step or in the following step, sheath 17 is also retracted away from the aperture to be occluded.

Aperture occlusion device 27 is then pulled taut against the defect such that four wire ribs 23*a–d* expand and contact the heart tissue around the defect. Optionally, sheath 17 is then pulled back further away from the proximal side of the defect (if that had not been done earlier), and deployment catheter 19 is retracted leaving device engaging catheter 13, release wire 15, and aperture occlusion device 27 in place and thus exposing aperture occlusion device half 27*b* on the proximal side of the defect, at which point the second half 27*b* of device 27 is deployed.

Once aperture occlusion device 27 is fully deployed, as seen in FIGS. 2-5, knuckle 15*a* is disengaged from eye 25 of aperture occlusion device 27, by retracting catheter 13 slightly from eye 25. The assembly including deployment catheter 19, device engaging catheter 13 and release wire 15 are then retracted from sheath 17. Finally, sheath 17 is also retracted from the body.

FIG. 2 depicts a perspective view of an aperture occlusion device, with 3 ribs, like that seen in FIG. 1, but fully deployed to occlude a defect or aperture 68 in wall 68*a*. Membranes 21*a* and 21*b* are supported by wire ribs 23*a–c* and 23'*a–c* respectively, which urge the membranes toward each other and connect the membranes with eye 25.

As seen in FIG. 3, membrane 21*a* is attached to three wire ribs 23*a*, *b* and *c* extending circumferentially then curving and radially extending to the center of membrane 21*a*. Ribs 23*a–c* attach at the center of membrane

21a and connect the pair to each other and to eye 25 which attaches to a release wire, not shown. Ribs 23a–c, upon thermal triggering of the memory retentive properties of the rib material (preferably nitinol), support and maintain the shape of membrane 21a. Membrane 21b is similarly retained by ribs 23'a–c.

FIG. 4 is a cross-section through plane 4—4 of FIG. 3. As depicted therein, membrane 21a is secured to rib 23a by glue 23c. Stitches, staples or the like may also be used to affix membrane 21a to rib 23a. Other configurations of ribs 23a, b, c may also be used.

FIG. 5 illustrates a cross-section along plane 5—5 of the aperture occlusion device of FIG. 3. Membranes 21a and 21b occlude aperture 68 in wall 68a, and are supported by wire ribs, 23a, b and 23'a, b, which urge the membranes toward each other and connect the membranes with eye 25.

FIG. 6 depicts septal defect 68' with a double helix occlusion device 62 partially deployed. Device 62 is introduced as a straight wire 64 through the assembly including, device engaging catheter 13 (like that shown in FIG. 1, but not shown in FIG. 6 due to limited space available), release wire 15 and sheath 17. Sheath 17 is dimetrically larger than device engaging catheter 13 to allow passage of device engaging catheter 13 therethrough. As with the assembly shown in and described with respect to FIG. 1, the assembly of release wire 15, device engaging catheter 13, wire 64 and sheath 17 are introduced through a large vein to and through the defect to be occluded. Sheath 17 optionally may be stopped short of defect 68' and may be withdrawn with device engaging catheter 13, as described, or independently of catheter 13.

Helix 62a is formed on the distal side of defect 68', preferably by the coiling of wire 64, nitinol for example, in response to a temperature change, upon body temperature contact or by retraction of spring steel into its "relaxed" (preprogrammed) configuration. A plurality of coils of progressively smaller diameter are formed, finally contacting the periphery of atrial wall 68a' surrounding defect 68' on the distal side thereof; each such coil of wire 64 contacts the previously formed coil above and below defect 68', such that helix 62a is deployed from the outside in, (relative to defect 68), until helix 62a is formed (as seen in FIG. 6).

The aperture occlusion device of FIG. 6 after deployment into the left atrium is seen in FIG. 9. The concentric circles are the result of the coiling of wire 64 (in this case from a very small starting circumference out) and also contacting the previously formed coil above and below defect 68', this time on the proximal side thereof.

After deploying helix 62a on the distal side of defect 68, sheath 17, device engaging catheter 13, release wire 15, and wire 64 are withdrawn equally and together to bring helix 62a into firm contact with the septal surface. As tension is maintained on wire 64 via release wire 15, sheath 17 is withdrawn over wire 64 and release wire 15, thereby exposing a length of wire 64 on the proximal side of the defect. Tension on wire 64 is then slowly reduced by advancing release wire 15 and sheath 17 equally and together. Wire 64 begins coiling at or near septal surface below defect 68. By progressively reducing tension on wire 64 (by repetitively withdrawing sheath 17 over release wire 15 and advancing sheath 17 and release wire 15 equally and together), successive coils are formed, each moving outward beyond the previously formed coil. Thus, helix 62b is formed from the inside out, until helix 62b is fully deployed as seen in FIGS. 7 and 8. Eye 25 is then disengaged from the release wire 15 (not shown), and the remaining apparatus is removed from the body as described with respect to FIG. 1.

In those embodiments dependent upon a thermally responsive change (such as with nitinol) as the means for effecting device deployment, it is desirable prior to deployment to continuously infuse a biocompatible fluid (such as normal saline) which is substantially below body temperature (for example at room temperature) through side port 19 of sheath 17 to maintain a thermal environment within sheath 17, that is below the transition temperature of the thermally responsive wire 64. This assures that wire 64 will not assume its programmed shape until it exits sheath 17.

Furthermore, the programmed deployed configuration of the double helix coil (in the embodiment of FIGS. 6–9) may preferably include shaping to urge the outermost coils of helices 62a and 62b inward toward the septal surface (and one another) to provide an increased frictional force between the helices and their respective septal surfaces.

By way of general description of the method of this invention, the device of the present invention may be used in a method of occluding an aperture within a body surface. A catheter, which can accommodate a wire in an elongated or folded configuration (optionally with an associated membrane), is introduced through a body member such as a femoral vein, deployed, for example, into the heart through the inferior vena cava and manipulated into position on the distal side of the aperture where the wire assumes its preprogrammed configuration including an occlusion-forming wire segment urged toward the aperture on the distal side of the septal defect. Withdrawing the catheter partially over the wire allows a substantial length of the wire to be exposed on the near side of the defect. Upon further deployment, the wire assumes a preprogrammed configuration including an occlusion-forming wire segment urged toward the aperture on the proximal side of the aperture. The wire is then disengaged from the means for holding it.

The device and method of this invention are believed to be particularly well adapted to occlude both atrial and ventricular septal defects, as well as other cardiovascular openings, such as a patent ductus arteriosus. The device (modified for tubal rather than aperture occlusion) is also well suited for use in occluding fallopian tubes.

In the embodiments disclosed, the finished structure comprises two connected occlusion-forming wire segments, disposed on opposite sides of an aperture, each formed of a wire resulting in helices, or domed members (with membranes attached to a wire frame), urged toward one another.

While this invention has been disclosed with reference to specific embodiments, it is apparent that other embodiments and equivalent variations of this invention may be devised by those skilled in the art without departing from the true spirit and scope of this invention. The appended claims are intended to be construed to include all such embodiments and equivalent variations.

What is claimed is:

1. A device adapted to occlude an aperture within a body surface, and adapted to be passed into said body, through a catheter and through said aperture, said device comprising a wire having two configurations, an elongated configuration for passage through said cathe-

ter and through said aperture, and a preprogrammed configuration which includes occlusion-forming wire segments one on each side of said aperture urged toward one another and means for causing said wire to change from said elongated configuration to said preprogrammed configuration inside said body, said means being a temperature responsive material of construction of said wire, by which said wire is activated at body temperature, to assume said preprogrammed configuration.

2. A device of claim 1 wherein said wire is combined with a catheter means for introducing said wire into said body, said catheter means also includes means for holding said wire, while it is in said catheter, at a temperature at which said wire does not tend to assume said preprogrammed configuration.

3. A device of claim 1 wherein said occlusion-forming segments each comprise helical coils urged toward one another.

4. A device of claim 1 wherein said wire further includes two foldable membranes, one associated with said first occlusion-forming wire segment and the other associated with said second occlusion-forming wire segment, said membranes in folded configuration being transportable through a catheter along with said wire, said wire adapted upon converting from said elongated configuration to said preprogrammed configuration to unfold said membranes and to form a frame supporting said membranes as essentially planar members, one disposed on each side of said aperture, and urged toward one another, wherein said means for causing a change in configuration is a thermally responsive material of construction.

5. A device according to claim 4 wherein said wire is secured to said membranes of said occlusion-forming wire segments.

6. A device according to claim 1, wherein said wire consists of nitinol.

7. A device according to claim 1, wherein said wire is biocompatible.

8. A device according to claim 1, wherein said wire is coated to enhance biocompatibility.

9. A device adapted to occlude an aperture within a body surface, and adapted to be passed into said body, through a catheter and through said aperture, said device comprising a wire having two configurations, an elongated configuration for passage through said catheter and through said aperture, and a preprogrammed configuration which includes occlusion-forming wire segments one on each side of said aperture, and means for causing said wire to change from said elongated configuration to said preprogrammed configuration inside said body, wherein said occlusion forming segments each comprise helical coils urged toward one another.

10. A device according to claim 9, wherein said wire consists of spring steel.

11. A method for occluding an aperture within a body surface by positioning the end of a catheter at the distal side of the aperture, deploying a wire of temperature responsive material of construction in an elongated configuration through said catheter to the distal side of said aperture with the aid of a means for holding said wire, permitting the wire exposed thereby to assume a preprogrammed configuration, including an occlusion-forming wire segment on the distal side of said aperture, and urged toward said aperture, withdrawing the end of said catheter through said aperture and deploying an additional length of said wire in an elongated configuration to be exposed on the proximal side of said aperture, whereupon said continued deployment, said wire is permitted to assume a preprogrammed configuration, including an opposing occlusion-forming wire segment urged toward said aperture on the proximal side of the aperture, and disengaging the wire from the means for holding said wire.

12. A method as recited in claim 11, wherein said defect is a atrial septal defect.

13. A method as recited in claim 11, wherein said defect is a ventricular septal defect.

14. A method as recited in claim 11, wherein said defect is a patent ductus arteriosus.

* * * * *

EXHIBIT C

UNITED STATES DISTRICT COURT
FOR THE DISTRICT COURT OF MASSACHUSETTS

NITINOL MEDICAL TECHNOLOGIES, INC. and LLOYD A. MARKS,
Plaintiffs,

v.

AGA MEDICAL CORPORATION,
Defendant.

Civ. No. 98-12506-NG

GERTNER, D.J.

ORDER RE: MOTION TO STAY
April 25, 2001

This action concerns United States Patent No. 5,105,420 ("the Marks patent"), which claims a new "aperture occlusion device" used to block the flow of blood through an opening between cavities in a human body. The plaintiffs, Nitinol Medical Technologies and Lloyd A. Marks ("Nitinol"), allege that defendant's products infringe one or more claims of the Marks patent. The defendant, AGA Medical Corporation ("AGA"), counters that the Marks patent is invalid in view of prior art.

One issue is not in dispute, however: The parties apparently agree that two pieces of purported prior art were not before the Patent Office ("PTO") when the Marks patent was originally prosecuted. To rectify this situation, Nitinol now seeks a stay of this action pending PTO reexamination of the Marks patent.

I agree with Nitinol that a stay will save both the parties' and the Court's resources, particularly as (1) many of the issues raised in this case (such as anticipation by prior art) may well be resolved by reexamination, (2) if I were to resolve any issues

at this time, the parties would likely have to relitigate some of the same issues following reexamination of the patent, and (3) although this case is several years old, document discovery is not yet complete, and deposition discovery has not begun. Accordingly, the plaintiffs' motion to stay this action pending reexamination of the Marks patent by the PTO [docket entry #110] is ALLOWED.

AGA is understandably concerned about this stay, as it could ultimately be found liable for infringement of the Marks patent during the period of the stay. In response to this concern, I note the following:

1. Claims amended during reexamination are only "entitled to the date of the original patent if they are without substantive change or are legally 'identical' to the claims in the original patent." Tennant Co. v. Hako Minuteman, Inc., 878 F.2d 1413, 1417 (Fed. Cir. 1989) (citing 35 U.S.C. § 307(b)).

2. Even if this Court ultimately determines that (1) the reexamined Marks patent claims are entitled to the date of the original patent, and (2) AGA is liable for infringement of the Marks patent during the period of the stay, it may still "be appropriate to limit prejudgment interest, or perhaps even deny it altogether," if I find the plaintiffs responsible for "undue delay in prosecuting [this] lawsuit." Allen Archery, Inc. v. Browning Manufacturing Co., 898 F.2d 787, 791 (Fed. Cir. 1990).

To further address AGA's concerns, I will continue to meet with the parties regularly during the stay, first to ensure that Nitinol moves expeditiously to obtain PTO reexamination of the Marks patent, and then to monitor the status of the reexamination process. To this end, a status conference is scheduled for Wednesday, October 10, 2001, at 2:30 p.m.

SO ORDERED.

Dated: April 25, 2001

NANCY GERTNER, U.S.D.J.

EXHIBIT D

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

NITINOL MEDICAL LABORITORIES, INC. ET AL. Plaintiffs,	)	
v.	)	C.A. No. 98-12506-NG
AGA MEDICAL CORPORATION, Defendant.	)	

GERTNER, D.J.:

ORDER OF DISMISSAL
December 1, 2003

The Defendant in this case moves to dismiss the Plaintiffs' Complaint in its letter dated September 30, 2003. [Document # 127]. The Defendant's request is GRANTED. The case is thus DISMISSED without prejudice.

SO ORDERED.

Dated: December 1, 2003

s/Nancy Gertner
NANCY GERTNER, U.S.D.J.

EXHIBIT E

Press Release

Source: NMT Medical, Inc.

NMT Medical Announces Favorable Decision by U.S. Patent Office Board of Appeals

Tuesday September 7, 3:16 pm ET

BOSTON, Sept. 7 /PRNewswire-FirstCall/ -- NMT Medical, Inc. (Nasdaq: NMTI - News) today announced a favorable decision by the U.S. Patent and Trademark Office Board of Appeals relating to the Company's patent infringement actions against AGA Medical Corp.

In December 1998, NMT filed a patent infringement suit against AGA Medical claiming that certain of AGA's products infringe U.S. Patent No. 5,108,420 (the '420 Patent), which is exclusively licensed by NMT. During the litigation, AGA identified certain third party patents that it argued would invalidate the claims of the '420 Patent. In September 2003, the Court dismissed NMT's suit against AGA without prejudice to NMT's ability to refile the suit after the conclusion of the reexamination proceedings.

Although a Patent Office examiner initially rejected the claims of the '420 Patent, the Patent Office Board of Appeals reversed the examiner's rejection of the claims on August 19, 2004 and returned the reexamination for action consistent with its decision.

John E. Ahern, NMT's President and CEO, said, "The Board of Appeals' decision represents an important step in our patent infringement efforts against AGA. As a medical technology innovator, NMT Medical has developed and obtained the rights to an impressive portfolio of patents and intellectual property that we will continue to defend aggressively."

About NMT Medical, Inc.

NMT Medical designs, develops and markets proprietary implant technologies that allow interventional cardiologists to treat cardiac sources of stroke and other brain attacks through minimally invasive, catheter-based procedures. NMT Medical is investigating the potential connection between a common cardiac defect called a patent foramen ovale (PFO) and brain attacks such as stroke, transient ischemic attacks (TIA's) and migraine headaches. A PFO can allow venous blood, unfiltered by the lungs, to enter the arterial circulation of the brain possibly triggering a cerebral event or brain attack. NMT is the leader in designing and developing implants to seal the PFO defect in a minimally invasive, catheter-based procedure performed by the interventional cardiologist.

Stroke is the third leading cause of death in the United States and leading cause of disability in adults. Each year 750,000 Americans suffer a new or recurrent stroke and 500,000 Americans experience a TIA. The prevalence of migraines in the United States is about 10%. Of the 28 million migraine sufferers in America, three out of four are women. Migraines have increased 50% in the last 20 years.

The Company also serves the pediatric interventional cardiologist with a broad range of cardiac

septal repair implants delivered with nonsurgical catheter techniques. For more information about NMT Medical, please visit http://www.nmtmedical.com.

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements – including statements regarding the timing and ultimate outcome of any administrative and litigation proceedings to enforce the Company's intellectual property rights and the Company's financial, sales and profitability expectations, expansion of the Company's cardiovascular business and market opportunities, including migraines and any other new applications for our technology or products, the timing, cost and outcome of CLOSURE I, expected patient enrollment levels and the timing thereof, regulatory approvals for the Company's products, new products and product developments -- involve known and unknown risks, uncertainties or other factors which may cause actual results, performance or achievements of the Company to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Factors that may cause such a difference include, but are not limited to, the risk factors discussed under the heading "Certain Factors That May Affect Future Results" included in Management's Discussion and Analysis of Financial Condition and Results of Operations in the Company's Annual Report on Form 10- K for the year ended December 31, 2003, as amended, and subsequent filings with the U.S. Securities and Exchange Commission.

Contact:
John E. Ahern
President & Chief Executive Officer
NMT Medical, Inc.
(617) 737-0930
jea@nmtmedical.com

Source: NMT Medical, Inc.

LAW OFFICES

INTERNATIONAL CENTRE
900 SECOND AVENUE SOUTH, SUITE 820
MINNEAPOLIS, MINNESOTA 55402-3313

TELEPHONE 612 339-7461
FACSIMILE 612 349 9556

Ck # 52077

RECEIVED

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CLERK
U.S. DIST. CT.
MPLS. MN

October 13, 2004

U.S. District Court for the District of Minnesota
U.S. Courthouse, Suite 202
300 South 4th St.
Minneapolis, MN 55415

Re: AGA Medical Corporation v. Nitinol Medical Technologies, Inc.
Our File No. 20040722.LAW

Dear Sir or Madam:

Enclosed for filing please find the original and two copies of the following documents:

1. Summons and Complaint and Exhibits; and

2. A check in the amount of $150.00 in the above captioned lawsuit.

Please date-stamp one (1) copy of the Summons and Complaint for our records.

If you have any questions related to the foregoing, please feel free to give me a call at (612) 339-7461.

Sincerely,

NIKOLAI & MERSEREAU, P.A.

James T. Nikolai

James T. Nikolai

JTN/acn
Enclosures

EXHIBIT D

CLOSED

United States District Court
District of Massachusetts (Boston)
CIVIL DOCKET FOR CASE #: 1:98-cv-12506-NG

Nitinol Medical Tech v. Aga Medical Corp.
Assigned to: Nancy Gertner
Demand: $0
Related Case: 1:04-cv-12565-NG
Cause: 35:271 Patent Infringement

Date Filed: 12/10/1998
Jury Demand: Defendant
Nature of Suit: 830 Patent
Jurisdiction: Federal Question

Plaintiff

Nitinol Medical Technologies Inc.

represented by **William F. Lee**
Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109
617-526-6556
Fax: 617-526-5000
Email: william.lee@wilmerhale.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

V.

Defendant

Aga Medical Corporation

represented by **James T. Nikolai**
Nikolai & Mersereau, P.A.
900 Second Avenue, South
Suite 820
Minneapolis, MN 55402-2813
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Paul T. Dietz
Nikolai, Mersereau & Dietz
900 Second Avenue South
820 International Centre
Minneapolis, MN 55402
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Thomas C. O'Konski
Cesari & McKenna, LLP
88 Black Falcon Avenue
Boston, MA 02210
617-951-2500

Fax: 617-951-3927
Email: TOK@c-m.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Counter Claimant

Aga Medical Corporation represented by **Thomas C. O'Konski**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

V.

Counter Defendant

Nitinol Medical Technologies Inc. represented by **William F. Lee**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Date Filed	#	Docket Text
12/10/1998	1	Complaint filed. Case assigned to Judge: Gertner. Receipt #: 10982 Amount:$ 150.00. Fee Status: pd (fmr) (Entered: 12/10/1998)
12/10/1998		Summons issued for Aga Medical Corp. (fmr) (Entered: 12/10/1998)
03/23/1999	2	Return of service executed as to Aga Medical Corp. with service on 3/22/99 filed. Answer due on 4/11/99 for Aga Medical Corp. (fmr) (Entered: 03/25/1999)
04/12/1999	3	Answer to complaint; jury demand and Counterclaim by Aga Medical Corp. against Nitinol Medical Tech , filed. (fmr) (Entered: 04/13/1999)
05/03/1999	4	Answer by Nitinol Medical Tech to [3-2] counter claim , filed. (fmr) (Entered: 05/04/1999)
05/11/1999	5	Motion by Aga Medical Corp. for Paul Dietz to appear pro hac vice fee status: pd fee amt: 50.00 Receipt #: 14215 , filed. (fmr) (Entered: 05/12/1999)
05/12/1999		Judge Nancy Gertner . Endorsed Order entered granting [5-1] motion for Paul Dietz to appear pro hac vice fee status: pd fee amt: 50.00 Receipt #: 14215 . (fmr) (Entered: 05/12/1999)
07/26/1999	6	Judge Nancy Gertner . Notice of Hearing/conference: set scheduling conference for 9:30 8/6/99 . (fmr) (Entered: 07/26/1999)
08/02/1999	7	Joint statement by Nitinol Medical Tech, Aga Medical Corp. , re: proposed discovery schedule, filed. (fmr) (Entered: 08/03/1999)
08/03/1999	8	Letter by Paul T. Dietz dated: 8/2/99 to: Mr McElwain re: problem with joint statement filed. (fmr) (Entered: 08/03/1999)

08/06/1999	9	Letter by Paul T. Dietz dated: 8/2/99 to: Mr MeElwain re: teleconference filed. (fmr) (Entered: 08/06/1999)
08/06/1999		Scheduling conference held . (fmr) (Entered: 08/10/1999)
08/06/1999	10	Judge Nancy Gertner . Clerk's Notes: re: scheduling conference, Counsel are to submit a new joint statement by 8/13/99. Judge will adopted as stated in conference set status conference for 2:30 7/11/00 Court Reporter: none (fmr) (Entered: 08/10/1999)
08/23/1999	11	Judge Nancy Gertner . Scheduling Order entered setting dispositive motion filing date of 12/31/00 . [EOD Date 8/24/99] (fmr) (Entered: 08/24/1999)
12/29/1999		Proposed protective order received and sent to chambers for signature (fmr) (Entered: 12/30/1999)
01/10/2000	12	Judge Nancy Gertner . Protective Order entered . [EOD Date 1/12/00] (fmr) (Entered: 01/12/2000)
01/31/2000	13	Joint motion by Nitinol Medical Tech, Aga Medical Corp. to modify discovery schedule , filed. . (fmr) (Entered: 02/03/2000)
02/20/2000		Judge Nancy Gertner . Endorsed Order entered granting [13-1] joint motion to modify discovery schedule, ready trial for 2/1/01 , set motion filing deadline for 10/31/00 . [EOD Date 2/22/00] dispositive motions, including Markman hearing due 12/29/00;cc/cl (sad) (Entered: 02/22/2000)
02/25/2000	14	Motion by Nitinol Medical Tech to compel , filed. (fmr) (Entered: 02/28/2000)
02/25/2000	15	Memorandum by Nitinol Medical Tech in support of [14-1] motion to compel , filed. (fmr) (Entered: 02/28/2000)
02/29/2000	16	Response by Aga Medical Corp. in opposition to [14-1] motion to compel , filed. (fmr) (Entered: 03/01/2000)
02/29/2000	16	Motion by Aga Medical Corp. to extend time to no date given to file opposition , filed. (fmr) (Entered: 03/01/2000)
03/06/2000	17	Motion by Nitinol Medical Tech for leave to file reply memorandum , filed. (fmr) (Entered: 03/07/2000)
03/06/2000	18	Reply/response by Nitinol Medical Tech to [16-1] opposition response , filed. (fmr) (Entered: 03/07/2000)
03/07/2000		Judge Nancy Gertner . Endorsed Order entered granting [17-1] motion for leave to file reply memorandum . [EOD Date 3/7/00] (fmr) (Entered: 03/07/2000)
03/10/2000		Judge Nancy Gertner . Endorsed Order entered granting [16-1] motion to extend time to no date given to file opposition. Motion is denied as to 7.1 (a)(2) grounds; the motion to extend time herby granted. Opposition to be filed by 3/23/00 [EOD Date 3/13/00] (fmr) (Entered: 03/13/2000)

03/23/2000	19	Response by Aga Medical Corp. in opposition to [14-1] motion to compel , filed. (fmr) (Entered: 03/24/2000)
03/23/2000	20	Motion by Aga Medical Corp. to compel in accordance with the stipulated protective order , filed. (fmr) (Entered: 03/24/2000)
03/23/2000	21	Memorandum by Aga Medical Corp. in support of [20-1] motion to compel in accordance with the stipulated protective order , filed. (fmr) (Entered: 03/24/2000)
03/23/2000	22	SEALED Appendix/exhibits by Aga Medical Corp. in support of [21-1] support memorandum , filed. (fmr) (Entered: 03/24/2000)
03/23/2000	23	Motion by Aga Medical Corp. for protective order , filed. (fmr) (Entered: 03/24/2000)
03/23/2000	24	Memorandum by Aga Medical Corp. in support of [23-1] motion for protective order , filed. (fmr) (Entered: 03/24/2000)
04/05/2000		Motion to compel sent to chambers #14 (fmr) (Entered: 04/05/2000)
04/06/2000	25	Motion by Nitinol Medical Tech for leave to file reply , filed. (fmr) (Entered: 04/10/2000)
04/06/2000	26	Response by Nitinol Medical Tech in opposition to [23-1] motion for protective order and reply to defendants opposition to motion to compel, filed. (fmr) (Entered: 04/10/2000)
04/06/2000	27	Response by Nitinol Medical Tech in opposition to [20-1] motion to compel in accordance with the stipulated protective order , filed. (fmr) (Entered: 04/10/2000)
04/06/2000	28	SEALED Exhibits by Nitinol Medical Tech [27-1] opposition response (fmr) (Entered: 04/10/2000)
04/10/2000		Judge Nancy Gertner . Endorsed Order entered granting [25-1] motion for leave to file reply . [EOD Date 4/10/00] (fmr) (Entered: 04/10/2000)
04/14/2000	29	Judge Nancy Gertner . ORDER entered: referral . referred Mag. Judge Robert B. Collings : [23-1] motion for protective order, [20-1] motion to compel in accordance with the stipulated protective order, [14-1] motion to compel . Purpose: ruling . (fmr) (Entered: 04/14/2000)
04/17/2000		Motion(s) no longer referred: [23-1] motion for protective order, [20-1] motion to compel in accordance with the stipulated protective order, [14-1] motion to compel . (fmr) (Entered: 04/18/2000)
04/17/2000	30	Mag. Judge Robert B. Collings . ORDER entered: referral . referred Mag. Judge David M. Cohen : [23-1] motion for protective order, [20-1] motion to compel in accordance with the stipulated protective order, [14-1] motion to compel . Purpose: determination . (fmr) (Entered: 04/18/2000)
05/01/2000	31	Motion by Aga Medical Corp. to stay all discovery and pretial deadlines , filed. (fmr) (Entered: 05/02/2000)

05/01/2000	32	Motion by Nitinol Medical Tech to extend time to to finish discovery , filed. (fmr) (Entered: 05/02/2000)
05/01/2000	38	Memorandum by Nitinol Medical Tech in support of [32-1] motion to extend time to to finish discovery , filed. (fmr) (Entered: 05/30/2000)
05/05/2000	33	Response by Aga Medical Corp. in opposition to [32-1] motion to extend time to to finish discovery , filed. (fmr) (Entered: 05/05/2000)
05/11/2000	35	Mag. Judge David M. Cohen . Clerk's Notes: re: preliminary teleconference. #23 m/supplemental protective order is denied. Further hearing to be set before Judge David Cohen on motions 14 and 20 (est 2-3hrs) Court Reporter: none (fmr) (Entered: 05/17/2000)
05/11/2000		Judge Nancy Gertner . Endorsed Order entered denying [23-1] motion for protective order . [EOD Date 5/17/00] (fmr) (Entered: 05/17/2000)
05/15/2000	34	Response by Nitinol Medical Tech in opposition to [31-1] motion to stay all discovery and pretial deadlines , filed. (fmr) (Entered: 05/16/2000)
05/17/2000		Tele-conference held . (fmr) (Entered: 05/17/2000)
05/17/2000	36	Motion by Aga Medical Corp. for leave to file reply , filed. (fmr) (Entered: 05/17/2000)
05/23/2000		Motion hearing re: [20-1] motion to compel in accordance with the stipulated protective order, [14-1] motion to compel (fmr) (Entered: 05/30/2000)
05/23/2000	39	Mag. Judge David M. Cohen . Clerk's Notes: re: motion hearing granting in part, denying in part [20-1] motion to compel in accordance with the stipulated protective order Court Reporter: Terry (fmr) (Entered: 05/30/2000)
05/26/2000		Judge Nancy Gertner . Endorsed Order entered granting [36-1] motion for leave to file reply . [EOD Date 5/26/00] (fmr) (Entered: 05/26/2000)
05/26/2000	37	Reply/response by Aga Medical Corp. to [34-1] opposition response , filed. (fmr) (Entered: 05/26/2000)
05/30/2000		Motion(s) no longer referred: [20-1] motion to compel in accordance with the stipulated protective order . (fmr) (Entered: 05/30/2000)
06/02/2000	40	Expert report of Harry Manbeck (fmr) (Entered: 06/05/2000)
06/06/2000	41	Motion by Nitinol Medical Tech for leave to file reply , filed. (fmr) (Entered: 06/08/2000)
06/06/2000	48	Reply/response by Nitinol Medical Tech to opposition to extened pre trial deadlines, filed. (fmr) (Entered: 06/13/2000)
06/08/2000		Judge Nancy Gertner . Endorsed Order entered granting [41-1] motion for leave to file reply . Reply is attached to motion for leave [EOD Date 6/8/00] (fmr) (Entered: 06/08/2000)
06/09/2000	42	Motion by Aga Medical Corp. for leave to file brief in excess of 20 pgs. ,

		filed. (fmr) (Entered: 06/09/2000)
06/09/2000		Judge Nancy Gertner . Endorsed Order entered granting [42-1] motion for leave to file brief in excess of 20 pgs. . [EOD Date 6/9/00] (fmr) (Entered: 06/09/2000)
06/09/2000	43	Motion by Aga Medical Corp. for summary judgment , filed. (fmr) (Entered: 06/09/2000)
06/09/2000	44	Memorandum by Aga Medical Corp. in support of [43-1] motion for summary judgment , filed. (fmr) (Entered: 06/09/2000)
06/09/2000	45	Affidavit of Paul T. Dietz , re: [44-1] support memorandum , filed. (fmr) (Entered: 06/09/2000)
06/09/2000	46	Motion by Aga Medical Corp. for sanctions , filed. (fmr) Modified on 06/09/2000 (Entered: 06/09/2000)
06/09/2000	47	Memorandum by Aga Medical Corp. in support of [46-1] motion for sanctions , filed. (fmr) (Entered: 06/09/2000)
06/20/2000	49	Motion by Aga Medical Corp. for leave to file reply , filed. (fmr) (Entered: 06/20/2000)
06/20/2000		Judge Nancy Gertner . Endorsed Order entered granting [49-1] motion for leave to file reply . [EOD Date 6/20/00] (fmr) (Entered: 06/20/2000)
06/20/2000	50	Response by Aga Medical Corp. in opposition to [48-1] reply , filed. (fmr) (Entered: 06/20/2000)
06/21/2000	51	Motion by Nitinol Medical Tech to extend time to 7/14/00 to respond to motion for s.j , filed. (fmr) (Entered: 06/22/2000)
06/22/2000	52	Response by Aga Medical Corp. in opposition to [51-1] motion to extend time to 7/14/00 to respond to motion for s.j , filed. (fmr) (Entered: 06/26/2000)
06/30/2000	53	Motion by Aga Medical Corp. under rule 41(b)to dismiss plaintiffs' claims , filed. c/s (fmr) (Entered: 07/06/2000)
07/10/2000	54	Status report by Nitinol Medical Tech regarding its motion to compel , filed. (fmr) (Entered: 07/10/2000)
07/10/2000	55	Motion by Aga Medical Corp. for joint determination and ruling of plaintiffs motion to compel and defendants motion to compel , filed. (fmr) (Entered: 07/10/2000)
07/10/2000	56	Motion by Aga Medical Corp. to compel , filed. (fmr) (Entered: 07/10/2000)
07/10/2000	57	Memorandum by Aga Medical Corp. in support of [56-1] motion to compel , filed. (fmr) (Entered: 07/10/2000)
07/14/2000	58	Response by Aga Medical Corp. in opposition to [54-1] status report , filed. (fmr) (Entered: 07/18/2000)

07/14/2000	59	Motion by Nitinol Medical Tech to seal/impound , filed. (fmr) (Entered: 07/18/2000)
07/14/2000	60	Motion by Nitinol Medical Tech for leave to file brief exceeding pg limit , filed. (fmr) (Entered: 07/18/2000)
07/14/2000	61	Memorandum by Nitinol Medical Tech in opposition to [43-1] motion for summary judgment , filed. (fmr) (Entered: 07/18/2000)
07/14/2000	62	SEALED Affidavit , re: [61-1] opposition memorandum , filed. (fmr) (Entered: 07/18/2000)
07/14/2000	63	Affidavit , re: [61-1] opposition memorandum , filed. (fmr) (Entered: 07/18/2000)
07/17/2000	64	Response by Nitinol Medical Tech in opposition to [46-1] motion for sanctions and to dismiss under rule 41(b), filed. c/s (fmr) (Entered: 07/19/2000)
07/18/2000		Judge Nancy Gertner . Endorsed Order entered granting [59-1] motion to seal/impound . [EOD Date 7/18/00] (fmr) (Entered: 07/18/2000)
07/18/2000		Judge Nancy Gertner . Endorsed Order entered granting [60-1] motion for leave to file brief exceeding pg limit . [EOD Date 7/18/00] (fmr) (Entered: 07/18/2000)
07/25/2000	65	Response by Nitinol Medical Tech in opposition to [56-1] motion to compel , filed. c/s (fmr) (Entered: 07/25/2000)
07/25/2000	66	Response by Nitinol Medical Tech in opposition to [55-1] motion for joint determination and ruling of plaintiffs motion to compel and defendants motion to compel , filed. (fmr) (Entered: 07/25/2000)
07/27/2000	67	Motion by Aga Medical Corp. for leave to file reply memorandum , filed. (fmr) (Entered: 08/01/2000)
08/01/2000	68	Response by Nitinol Medical Tech in opposition to [66-1] opposition response , filed. (fmr) (Entered: 08/01/2000)
08/04/2000	69	Motion by Aga Medical Corp. for leave to file reply brief , filed. (fmr) (Entered: 08/07/2000)
08/04/2000	70	SEALED Reply/response by Aga Medical Corp. to [66-1] opposition response , filed. (fmr) (Entered: 08/07/2000)
08/07/2000		Judge Nancy Gertner . Endorsed Order entered granting [69-1] motion for leave to file reply brief . [EOD Date 8/7/00] (fmr) (Entered: 08/07/2000)
08/09/2000	71	Judge Nancy Gertner . ORDER entered: referral . referred Mag. Judge Judith G. Dein : [56-1] motion to compel, [55-1] motion for joint determination and ruling of plaintiffs motion to compel and defendants motion to compel, [14-1] motion to compel . Purpose: ruling . (fmr) (Entered: 08/14/2000)

08/21/2000		Terminated document: terminating [51-1] motion to extend time to 7/14/00 to respond to motion for s.j . Motion is moot, response has been filed (fmr) (Entered: 08/21/2000)
08/22/2000	74	Mag. Judge Robert B. Collings . Notice of Hearing/conference: Motion hearing before Mag. Judge Robert B. Collings set for 2:00 9/12/00 for [14-1] motion to compel . (fmr) (Entered: 08/25/2000)
08/23/2000	72	Motion by Aga Medical Corp. for leave to file reply memo , filed. (fmr) (Entered: 08/25/2000)
08/23/2000	73	Reply/response by Aga Medical Corp. to [64-1] opposition response , filed. (fmr) (Entered: 08/25/2000)
08/25/2000		Judge Nancy Gertner . Endorsed Order entered granting [72-1] motion for leave to file reply memo . [EOD Date 8/25/00] (fmr) (Entered: 08/25/2000)
08/28/2000		Judge Nancy Gertner . Endorsed Order entered denying [53-1] motion under rule 41(b)to dismiss plaintiffs' claims . [EOD Date 8/30/00] (fmr) (Entered: 08/30/2000)
08/28/2000		Judge Nancy Gertner . Endorsed Order entered mooting [51-1] motion to extend time to 7/14/00 to respond to motion for s.j . [EOD Date 8/30/00] (fmr) (Entered: 08/30/2000)
09/06/2000		Judge Nancy Gertner . Endorsed Order entered granting [67-1] motion for leave to file reply memorandum . [EOD Date 9/6/00] (mcm) (Entered: 09/06/2000)
09/13/2000		Motion hearing re: [56-1] motion to compel, [55-1] motion for joint determination and ruling of plaintiffs motion to compel and defendants motion to compel (fmr) (Entered: 09/18/2000)
09/13/2000	75	Mag. Judge Judith G. Dein . Clerk's Notes: re: motion hearing held on dates 9/13, by 9/21/00 responses due, 9/28/00 parties status report regarding interrogs, 9/29/00 plts memo on privlege, 10/10/00 plts shall produce any docs to modified request Court Reporter: Tape (fmr) (Entered: 09/18/2000)
09/14/2000		Mag. Judge Judith G. Dein . Endorsed Order entered granting in part, denying in part [14-1] motion to compel . See order [EOD Date 9/18/00] (fmr) (Entered: 09/18/2000)
09/14/2000		Mag. Judge Judith G. Dein . Endorsed Order entered granting in part, denying in part [56-1] motion to compel . See order [EOD Date 9/18/00] (fmr) (Entered: 09/18/2000)
09/14/2000		Mag. Judge Judith G. Dein . Endorsed Order entered granting [55-1] motion for joint determination and ruling of plaintiffs motion to compel and defendants motion to compel . [EOD Date 9/18/00] (fmr) (Entered: 09/18/2000)
09/14/2000	76	Mag. Judge Judith G. Dein . Order entered granting in part, denying in

		part [14-1] motion to compel granting in part, denying in part [56-1] motion to compel . [EOD Date 9/18/00] (fmr) (Entered: 09/18/2000)
09/29/2000	77	Supplemental Memorandum by Nitinol Medical Tech in support of [14-1] motion to compel , pursuant to order issued by Mag Dein filed. (fmr) (Entered: 10/03/2000)
10/10/2000	78	Status report on discovery by Nitinol Medical Tech, Aga Medical Corp. , filed. (fmr) (Entered: 10/10/2000)
10/13/2000	79	Motion by Aga Medical Corp. to bifurcate trial , filed. (fmr) (Entered: 10/13/2000)
10/13/2000	80	Response by Aga Medical Corp. in opposition to [73-1] reply , filed. (fmr) (Entered: 10/13/2000)
10/16/2000		Tele-conference held . (fmr) (Entered: 10/17/2000)
10/16/2000	81	Mag. Judge Judith G. Dein . Clerk's Notes: re: discovery issues. Court hears from the parties and will issue an order Court Reporter: Tape (fmr) (Entered: 10/17/2000)
10/17/2000	83	Mag. Judge Judith G. Dein . Supplemental Order on Motion to compel entered . [EOD Date 10/23/00] (fmr) (Entered: 10/23/2000)
10/18/2000	82	Mag. Judge Judith G. Dein . Notice of Hearing/conference: Motion hearing before Mag. Judge Judith G. Dein set for 10:00 10/31/00 for [32-1] motion to extend time to to finish discovery, set for 10:00 10/31/00 for [31-1] motion to stay all discovery and pretial deadlines . (fmr) (Entered: 10/18/2000)
10/26/2000	84	Mag. Judge Judith G. Dein . Supplemental Memorandum and Order on motion to compel regarding waiver of atty- client privilege entered. [EOD Date 10/26/00] (fmr) (Entered: 10/26/2000)
10/30/2000	85	Memorandum by Nitinol Medical Tech in opposition to [79-1] motion to bifurcate trial , filed. (fmr) (Entered: 11/01/2000)
10/31/2000	86	Mag. Judge Judith G. Dein . Order entered denying [31-1] motion to stay all discovery and pretial deadlines granting in part, denying in part [32-1] motion to extend time to to finish discovery . [EOD Date 11/6/00] (fmr) (Entered: 11/06/2000)
10/31/2000		Mag. Judge Judith G. Dein . Endorsed Order entered granting in part, denying in part [32-1] motion to extend time to to finish discovery . Extended discovery schedule to be set at a later date [EOD Date 11/6/00] (fmr) (Entered: 11/06/2000)
10/31/2000		Mag. Judge Judith G. Dein . Endorsed Order entered denying [31-1] motion to stay all discovery and pretial deadlines, after hearing . [EOD Date 11/6/00] (fmr) (Entered: 11/06/2000)
11/01/2000		Motion to bifurcate sent to chambers with oppositon (fmr) (Entered: 11/01/2000)

11/03/2000	89	Statement of counsel filed by Aga Medical Corp. , Re: position statement. (fmr) (Entered: 11/09/2000)
11/07/2000	87	Statement of counsel filed by Nitinol Medical Tech , Re: prior art. (fmr) (Entered: 11/08/2000)
11/08/2000	88	Mag. Judge Judith G. Dein . Order entered, amending [84-1] memorandum order . [EOD Date 11/9/00] (fmr) (Entered: 11/09/2000)
11/09/2000	90	Notice of change of address filed by Thomas C. O'Konski by Aga Medical Corp. . (fmr) (Entered: 11/09/2000)
11/15/2000	91	Status report by Nitinol Medical Tech , filed. (fmr) (Entered: 11/20/2000)
11/15/2000	92	Affidavit , re: [91-1] status report , filed. (fmr) (Entered: 11/20/2000)
11/15/2000	93	Affidavit , re: [91-1] status report , filed. (fmr) (Entered: 11/20/2000)
11/21/2000	95	Motion by Aga Medical Corp. for protective order , filed. (fmr) (Entered: 11/28/2000)
11/22/2000	94	Mag. Judge Judith G. Dein . Order entered, compelling production of discovery and discovery schedule . [EOD Date 11/28/00] (fmr) (Entered: 11/28/2000)
12/01/2000	96	Motion by Nitinol Medical Tech to extend time to no date given to respond to motion to compel , filed. (fmr) (Entered: 12/06/2000)
12/01/2000	97	Response by Nitinol Medical Tech in opposition to [95-1] motion for protective order , filed. (fmr) (Entered: 12/06/2000)
12/06/2000	98	Statement of counsel filed by Nitinol Medical Tech , Re: discovery. (fmr) (Entered: 12/06/2000)
12/06/2000	99	Statement of counsel filed by Aga Medical Corp. , Re: proposed discovery schedule. (fmr) (Entered: 12/06/2000)
12/07/2000	100	Statement of counsel filed by Nitinol Medical Tech , Re: discovery schedule. (fmr) (Entered: 12/07/2000)
12/07/2000	101	Mag. Judge Judith G. Dein . Order entered granting in part, denying in part [95-1] motion for protective order . [EOD Date 12/7/00] (fmr) (Entered: 12/07/2000)
12/07/2000		Mag. Judge Judith G. Dein . Endorsed Order entered granting [96-1] motion to extend time to no date given to respond to motion to compel . [EOD Date 12/7/00] (fmr) (Entered: 12/07/2000)
12/07/2000		Mag. Judge Judith G. Dein . Endorsed Order entered granting in part, denying in part [95-1] motion for protective order . [EOD Date 12/7/00] (fmr) (Entered: 12/07/2000)
12/15/2000	102	FAXED Letter by Paul T. Dietz dated: 12/15/00 to: Judge Dein re: proposed order filed. (fmr) (Entered: 12/22/2000)
12/20/2000	104	Letter dated: 12/20/00 to: Tom re: fax of proposed order filed. (fmr)

		(Entered: 12/26/2000)
12/21/2000	103	Mag. Judge Judith G. Dein . Order entered . [EOD Date 12/26/00] (fmr) (Entered: 12/26/2000)
01/16/2001	105	Judge Nancy Gertner . Notice of Hearing/conference: set status conference for 2:30 2/1/01 . (fmr) (Entered: 01/17/2001)
01/24/2001	106	Motion by Aga Medical Corp. for summary judgment , filed. (fmr) (Entered: 01/24/2001)
01/24/2001	107	Motion by Aga Medical Corp. for sanctions , filed. (fmr) (Entered: 01/24/2001)
01/24/2001	108	Memorandum by Aga Medical Corp. in support of [107-1] motion for sanctions , filed. (fmr) (Entered: 01/24/2001)
01/24/2001		Judge Nancy Gertner . Endorsed Order entered denying [46-1] motion for sanctions, at this time . [EOD Date 1/25/01] (fmr) (Entered: 01/25/2001)
01/24/2001		Judge Nancy Gertner . Endorsed Order entered denying [43-1] motion for summary judgment . [EOD Date 1/25/01] (fmr) (Entered: 01/25/2001)
01/24/2001		Judge Nancy Gertner . Endorsed Order entered denying [79-1] motion to bifurcate trial . [EOD Date 1/25/01] (fmr) (Entered: 01/25/2001)
02/01/2001		Status conference held . (fmr) (Entered: 02/06/2001)
02/01/2001	109	Judge Nancy Gertner . Clerk's Notes: re: status conference . plt request a stay, dft object. Judge adopts J Deins 12/21/00 order. Pltf will file an oppostion to summary judgment and an assetned to motion for stay on or before 2/16/01. Trial anticipated for around 12/01 Court Reporter: none (fmr) (Entered: 02/06/2001)
02/20/2001	110	Motion by Nitinol Medical Tech to stay , filed. (fmr) (Entered: 02/20/2001)
02/20/2001	111	Response by Nitinol Medical Tech in opposition to [106-1] motion for summary judgment , filed. (fmr) (Entered: 02/20/2001)
02/20/2001	111	Memorandum by Nitinol Medical Tech in support of [110-1] motion to stay , filed. (fmr) (Entered: 02/20/2001)
02/20/2001	112	Affidavit of Lloyd Marks , re: [111-1] support memorandum, [111-1] opposition response , filed. (fmr) (Entered: 02/20/2001)
02/20/2001	113	Affidavit of Morris Simon , re: [111-1] support memorandum, [111-1] opposition response , filed. (fmr) (Entered: 02/20/2001)
03/02/2001	114	Memorandum by Aga Medical Corp. in opposition to [110-1] motion to stay , filed. (fmr) (Entered: 03/02/2001)
03/02/2001	115	Motion by Aga Medical Corp. for leave to file reply memo , filed. (fmr) (Entered: 03/02/2001)
03/02/2001		Motion for leave #115 sent to chambers with proposed filing (fmr)

		(Entered: 03/02/2001)
03/02/2001		Motion to stay #114 and motion for summary judgment #106 sent to chambers for ruling with oppositions (fmr) (Entered: 03/02/2001)
03/29/2001	116	Motion by Nitinol Medical Tech for leave to file reply to opposition , filed. (fmr) (Entered: 03/29/2001)
03/29/2001		Motion for leave # 116 and proposed filing sent to chambers (fmr) (Entered: 03/29/2001)
04/10/2001	117	Response by Aga Medical Corp. in opposition to [116-1] motion for leave to file reply to opposition , filed. (eaf) (Entered: 04/10/2001)
04/10/2001		Status conference set at 2:00 4/25/01 before Judge Nancy Gertner. All parties notified by telephone on 4/10/01. (mcm) (Entered: 04/10/2001)
04/25/2001		Motion hearing re: [110-1] motion to stay. (eaf) (Entered: 04/26/2001)
04/25/2001	118	Judge Nancy Gertner . Clerk's Notes: re: motion to stay, set status conference for 2:30 10/10/01 Will draft stay order. Stay contingent on reexamination being prosecuted expeditiously. Motions not termed; case closed administratively pending reprosectuion of patent. (eaf) (Entered: 04/26/2001)
04/25/2001	119	Judge Nancy Gertner . Order entered granting [110-1] motion to stay . [EOD Date 4/26/01] (eaf) (Entered: 04/26/2001)
04/26/2001		CASE NO LONGER REFERRED TO . (eaf) (Entered: 04/26/2001)
04/26/2001		Motion(s) no longer referred: [116-1] motion for leave to file reply to opposition, [115-1] motion for leave to file reply memo, [110-1] motion to stay, [107-1] motion for sanctions, [106-1] motion for summary judgment, [96-1] motion to extend time to no date given to respond to motion to compel, [95-1] motion for protective order, [79-1] motion to bifurcate trial, [72-1] motion for leave to file reply memo, [69-1] motion for leave to file reply brief, [67-1] motion for leave to file reply memorandum, [60-1] motion for leave to file brief exceeding pg limit, [59-1] motion to seal/impound, [56-1] motion to compel, [55-1] motion for joint determination and ruling of plaintiffs motion to compel and defendants motion to compel, [53-1] motion under rule 41(b)to dismiss plaintiffs' claims, [51-1] motion to extend time to 7/14/00 to respond to motion for s.j, [49-1] motion for leave to file reply, [46-1] motion for sanctions, [43-1] motion for summary judgment, [42-1] motion for leave to file brief in excess of 20 pgs., [41-1] motion for leave to file reply, [36-1] motion for leave to file reply, [32-1] motion to extend time to to finish discovery, [31-1] motion to stay all discovery and pretial deadlines, [25-1] motion for leave to file reply, [23-1] motion for protective order, [20-1] motion to compel in accordance with the stipulated protective order, [17-1] motion for leave to file reply memorandum, [16-1] motion to extend time to no date given to file opposition, [14-1] motion to compel, [13-1] joint motion to modify discovery schedule, [5-1] motion for Paul Dietz to appear pro hac vice fee status: pd fee amt: 50.00 Receipt #:

		14215 . (eaf) (Entered: 04/26/2001)
04/26/2001		Case closed. (eaf) (Entered: 04/26/2001)
10/02/2001	120	Consented to Motion by Aga Medical Corp. for James T. Nikolai to appear pro hac vice fee status: pd fee amt: $50.00 Receipt #: 34179 , filed. c/s. (jf) (Entered: 10/03/2001)
10/02/2001	121	Certificate of Good Standing by Attorney James T. Nikolai, filed. (jf) (Entered: 10/03/2001)
10/03/2001		Judge Nancy Gertner . Endorsed Order entered granting [120-1] motion for James T. Nikolai to appear pro hac vice fee status: pd fee amt: $50.00 Receipt #: 34179 Added James T. Nikolai. cc:cl. [EOD Date 10/3/01] (jf) (Entered: 10/03/2001)
10/10/2001		Status conference held . (jf) (Entered: 10/11/2001)
10/10/2001	122	Judge Nancy Gertner . Clerk's Notes: re: Telephone Conference Held., Set status conference for 3:00 4/30/02 , by telephone if requested. Stayed continued until 4/30/02 by the consent of all parties. Court Reporter: None (jf) (Entered: 10/11/2001)
05/02/2002	123	Judge Nancy Gertner . Clerk's Notes: re: Telephone Conference Held; ORDERED: Case stayed until 10/31/02; parties in agreement that case is Administratively closed until patent office issues an opinion on outstanding claims. Judge Gertner will consider dismissing(w/out prejudice) case if the patent office delays issuing their decision past 2002, Set status conference for 2:30 10/31/02 Court Reporter: None (jf) (Entered: 05/14/2002)
10/31/2002		Telephone/Status conference held. (jf) (Entered: 11/01/2002)
10/31/2002	124	Judge Nancy Gertner. Clerk's Notes: re: Telephone Conference Held; Set status conference for 2:15 2/26/02 (jf) (Entered: 11/01/2002)
02/27/2003	125	Judge Nancy Gertner. Notice of Hearing/conference: Set telephone status conference for 2:15 3/18/03 . Notice mailed to counsel. (jf) (Entered: 02/28/2003)
03/18/2003		Telephone conference held. (jf) (Entered: 03/19/2003)
03/18/2003	126	Judge Nancy Gertner . Clerk's Notes: re: telephone conference held; case stayed for 60 days; counsel will submit a proposed order forthwith. Court Reporter: none (jf) (Entered: 03/19/2003)
09/30/2003	127	Letter (non-motion) from Thomas C. O'Konski to Judge Gertner re: patent-in-suit before the US Patent and Trademark Office, filed. (sent to chambers) (Filo, Jennifer) (Entered: 10/06/2003)
10/03/2003	128	Letter/request (non-motion) from Dominic E. Massa to Judge Gertner re: Letter dated 9/30/03 by Thomas C. O'Konski, filed. (sent to chambers w/#127) (Filo, Jennifer) (Entered: 10/06/2003)
10/16/2003		Electronic Clerk's Notes for proceedings held before Judge Nancy

		Gertner : TELEPHONE CONFERENCE HELD, parties report status of case. Ordered: judge will reconsider dft's motion to dismiss, matters taken under advisement.. (Court Reporter none.) (Molloy, Maryellen) (Entered: 10/16/2003)
12/01/2003	129	Judge Nancy Gertner : ORDER OF DISMISSAL entered (Filo, Jennifer) (Entered: 12/02/2003)

PACER Service Center			
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03/09/2005 11:50:27			
PACER Login:	hd0009	Client Code:	
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Billable Pages:	8	Cost:	0.64

EXHIBIT E

UNITED STATES DISTRICT COURT
FOR THE DISTRICT COURT OF MASSACHUSETTS

NITINOL MEDICAL TECHNOLOGIES, INC. and LLOYD A. MARKS,
Plaintiffs,

v.

AGA MEDICAL CORPORATION,
Defendant.

Civ. No. 98-12506-NG

GERTNER, D.J.

ORDER RE: MOTION TO STAY
April 25, 2001

This action concerns United States Patent No. 5,105,420 ("the Marks patent"), which claims a new "aperture occlusion device" used to block the flow of blood through an opening between cavities in a human body. The plaintiffs, Nitinol Medical Technologies and Lloyd A. Marks ("Nitinol"), allege that defendant's products infringe one or more claims of the Marks patent. The defendant, AGA Medical Corporation ("AGA"), counters that the Marks patent is invalid in view of prior art.

One issue is not in dispute, however: The parties apparently agree that two pieces of purported prior art were not before the Patent Office ("PTO") when the Marks patent was originally prosecuted. To rectify this situation, Nitinol now seeks a stay of this action pending PTO reexamination of the Marks patent.

I agree with Nitinol that a stay will save both the parties' and the Court's resources, particularly as (1) many of the issues raised in this case (such as anticipation by prior art) may well be resolved by reexamination, (2) if I were to resolve any issues

at this time, the parties would likely have to relitigate some of the same issues following reexamination of the patent, and (3) although this case is several years old, document discovery is not yet complete, and deposition discovery has not begun. Accordingly, the plaintiffs' motion to stay this action pending reexamination of the Marks patent by the PTO [docket entry #110] is **ALLOWED.**

AGA is understandably concerned about this stay, as it could ultimately be found liable for infringement of the Marks patent during the period of the stay. In response to this concern, I note the following:

1. Claims amended during reexamination are only "entitled to the date of the original patent if they are without substantive change or are legally 'identical' to the claims in the original patent." Tennant Co. v. Hako Minuteman, Inc., 878 F.2d 1413, 1417 (Fed. Cir. 1989) (citing 35 U.S.C. § 307(b)).

2. Even if this Court ultimately determines that (1) the reexamined Marks patent claims are entitled to the date of the original patent, and (2) AGA is liable for infringement of the Marks patent during the period of the stay, it may still "be appropriate to limit prejudgment interest, or perhaps even deny it altogether," if I find the plaintiffs responsible for "undue delay in prosecuting [this] lawsuit." Allen Archery, Inc. v. Browning Manufacturing Co., 898 F.2d 787, 791 (Fed. Cir. 1990).

To further address AGA's concerns, I will continue to meet with the parties regularly during the stay, first to ensure that Nitinol moves expeditiously to obtain PTO reexamination of the Marks patent, and then to monitor the status of the reexamination process. To this end, a status conference is scheduled for Wednesday, October 10, 2001, at 2:30 p.m.

SO ORDERED.

Dated: April 25, 2001

NANCY GERTNER, U.S.D.J.

EXHIBIT F

06/25/01

90/006043

06/25/01

PTO/SB/57 (02-01)
Approved for use through 07/31/2004. OMB 0651-0033
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

(Also referred to as FORM PTO - 1465)

REQUEST FOR *EX PARTE* REEXAMINATION TRANSMITTAL FORM

Address to:
Assistant Commissioner for Patents
Box Reexam
Washington, D.C. 20231

Attorney Docket No. 000365-00002

Date: June 25, 2001

1. [X] This is a request for *ex parte* reexamination pursuant to 37 CFR 1.510 of patent number 5,108,420 issued April 28, 1992. The request is made by:

   [X] patent owner. [ ] third party requester.

2. [X] The name and address of the person requesting reexamination is:
   Lloyd Marks, M.D.
   1021 Minisink Way
   Westfield, New Jersey 07090 USA

3. [X] a. A check in the amount of $2520 is enclosed to cover the reexamination fee, 37 CFR 1.20(c)(1);

   [ ] b. The Commissioner is hereby authorized to charge the fee as set forth in 37 CFR 1.20(c)(1) to Deposit Account No. _____; or

   [ ] c. Payment by credit card. Form PTO-2038 is attached.

4. [X] Any refund should be made by [X] check or [ ] credit to Deposit Account No. 23-2185. 37 CFR 1.26(c). If payment is made by credit card, refund must be to credit card account.

5. [X] A copy of the patent to be reexamined having a double column format on one side of a separate paper is enclosed. 37 CFR 1.510(b)(4)

6. [ ] CD-ROM or CD-R in duplicate, Computer Program (Appendix) or large table

7. [ ] Nucleotide and/or Amino Acid Sequence Submission
   If applicable, all of the following are necessary
   a. [ ] Computer Readable Form (CRF)
   b. Specification Sequence Listing on:
      i [ ] CD-ROM (2 copies) or CD-R (2 copies); or
      ii [ ] paper
   c. [ ] Statements verifying identity of above copies

8. [ ] A copy of any disclaimer, certificate of correction or reexamination certificate issued in the patent is included.

9. [X] Reexamination of claim(s) 1-14 is requested.

10. [X] A copy of every patent or printed publication relied upon is submitted herewith including a listing thereof on Form PTO-1449.

11. [X] An English language translation of all necessary and pertinent non-English language patents and/or printed publications is included.

06/26/2001 MGUITH 00000003 90006043
01 FC:147 2520.00 OP

PTO/SB/57 (02-01)
Approved for use through 01/31/2004. OMB 0651-0033
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

12. [x] The attached detailed request includes at least the following items:
   a. A statement identifying each substantial new question of patentability based on prior patents and printed publications. 37 CFR 1.510(b)(1)
   b. An identification of every claim for which reexamination is requested, and a detailed explanation of the pertinency and manner of applying the cited art to every claim for which reexamination is requested. 37 CFR 1.510(b)(2)

13. [ ] A proposed amendment is included (only where the patent owner is the requester). 37 CFR 1.510(e)

14. [ ] a. It is certified that a copy of this request (if filed by other than the patent owner) has been served in its entirety on the patent owner as provided in 37 CFR 1.33(c). The name and address of the party served and the date of service are:

_____

_____

_____

Date of Service:_____; or

[ ] b. A duplicate copy is enclosed since service on patent owner was not possible.

15. [x] Correspondence Address: Direct all communication about the reexamination to:

[x] Customer Number 002779 → *Place Customer Number Bar Code Label here*

OR *Type Customer Number here*

[x] Firm or Individual Name	George C. Myers, Jr.				
Address (line 1)	Blank Rome Comisky & McCauley LLP				
Address (line 2)	The Farragut Bldg., 900 17th St., N.W.				
City	Washington	State	DC	Zip	20006
Country	U.S.A.				
Telephone	(202) 530-7400	Fax	(202) 463-6915		

16. [x] The patent is currently the subject of the following concurrent proceeding(s):
   [ ] a. Copending reissue Application No._____.
   [ ] b. Copending reexamination Control No._____.
   [ ] c. Copending Interference No._____.
   [x] d. Copending litigation styled:
   Nitinol Medical Technologies, Inc. et al. v. AGA Medical Corp, Civil Action No. 98-12506 (NG)

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

George C. Myers

Authorized Signature

June 25, 2001

Date

[x] *For Patent Owner Requester*

[ ] *For Third Party Requester*

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reexamination of U.S. Patent of	)	
	)	
Lloyd A. Marks	)	
	)	
Patent No. 5,108,420	)	Atty Docket No.: 000365-00002
	)	
Issue Date: April 28, 1992	)	
	)	
For: APERTURE OCCLUSION DEVICE	)	

REQUEST FOR *EX PARTE* REEXAMINATION

Honorable Commissioner of Patents
Box Reexam
Washington, D.C. 20231

Sir:

Ex parte reexamination under 35 U.S.C. §§302-307 and 37 C.F.R. §1.510 is requested for United States Patent No. 5,108,420 ("the Marks patent"). A copy of the Marks patent is submitted with this request. The Marks patent is still in force and is the subject of a pending civil action for patent infringement styled *Nitinol Medical Tech., Inc. and Lloyd A. Marks v. AGA Medical Corp.*, U.S. District Court, District of Massachusetts, Civil Action No.: CV 98-12506-NG ("the NMT litigation"), which has been stayed pending the outcome of this reexamination. The Plaintiff Nitinol in the NMT litigation is the exclusive licensee of the patent owner, the Plaintiff Marks.

I. Service

The present Request for Reexamination is filed by the patent owner. Service on the pater owner is therefore not required.

II. Claims for Which Reexamination is Requested

Reexamination is requested for claims 1-14 of the Marks patent in view of the following documents which have not been previously considered by the United States Patent and Trademark Office (USPTO):

(1) U.S. Patent No. 5,192,301 issued on March 9, 1993 to Kamiya et al. and claiming a foreign priority date of January 17, 1989 ("Kamiya et al.").

(2) German Publication DD 233 303 A1 published on or about February 26, 1986 ("German '303").

Copies of each of these documents are submitted with this Request together with an English translation of the German '303 publication prepared by the Defendant AGA in the NMT litigation. The patent owner does not certify the accuracy of the English translation submitted herewith and, if appropriate, the patent owner will submit his English translation of the entire German '303 or disputed portions thereof after this reexamination request is granted.

III. Substantial New Question of Patentability

A substantial new question of patentability exists if the teaching of a prior art patent or printed publication is such that a reasonable examiner would consider the teaching to be important in deciding whether or not a claim is patentable, and the same question of patentability as to that claim has not been decided by the USPTO in a previous examination or in a final holding of invalidity by a federal court in a decision on the merits involving the claim. Kamiya et al. and German '303 are not of record in the prosecution file of the Marks patent, and therefore, were presumably not considered by the examiner. They both disclose plug devices used for closing or occluding a body defect, opening or blood vessel, that include shape memory elements. The Marks patent includes claims directed to devices that may use shape memory alloys to form opposed wire

segments which are urged toward one another in a preprogrammed configuration for occluding apertures in body surfaces. The Defendant AGA in the NMT litigation has alleged that Kamiya et al. and German '303 anticipate all the claims of the Marks patent. The patent owner does not agree that Kamiya et al. or German '303 anticipates any claim of the Marks patent, or renders any claim of the Marks patent obvious if combined with the other or with any other prior art. However, based on the assumption that Defendant AGA's allegation of invalidity is made in good faith, Kamiya et al. and German '303 present a substantial new question of patentability as required by 37 CFR §1.510(b)(1).

IV. Pertinency of Prior Art

Claim 1 of the Marks patent is directed to a device adapted to occlude an aperture within a body surface, which is adapted to be passed into the body through a catheter and through the aperture. The device as claimed in claim 1 has a wire having two configurations, an elongate configuration for passing through the catheter and aperture, and a preprogrammed configuration that includes wire segments on each side of the aperture that are formed to be urged toward one another and occlude the aperture and means for causing the wire to change from the elongated configuration to the preprogrammed configuration in the body. The Defendant AGA contends that Kamiya et al. and German '303 disclose aperture occluding devices with occlusion-forming wire segments that are urged toward one another.

V. Conclusion

Although the patent owner disagrees that either of Kamiya et al. or German '303 render any claim of the Marks patent unpatentable, for the foregoing reasons, it is respectfully submitted that a substantial new question of patentability exists with respect to at least one claim of the Marks

a substantial new question of patentability exists with respect to at least one claim of the Marks patent. Accordingly, it is respectfully requested that this Request for *Ex Parte* Reexamination be granted.

Respectfully submitted,

George C. Myers, Jr.
Registration No. 27,040
Attorney for the Patent Owner

BLANK ROME COMISKY & MCCAULEY, LLP
Customer No. 002779
The Farragut Building, Suite 1000
900 17th Street, N.W.
Washington, D.C. 20006
Telephone: (202) 530-7400

Date: June 25, 2001

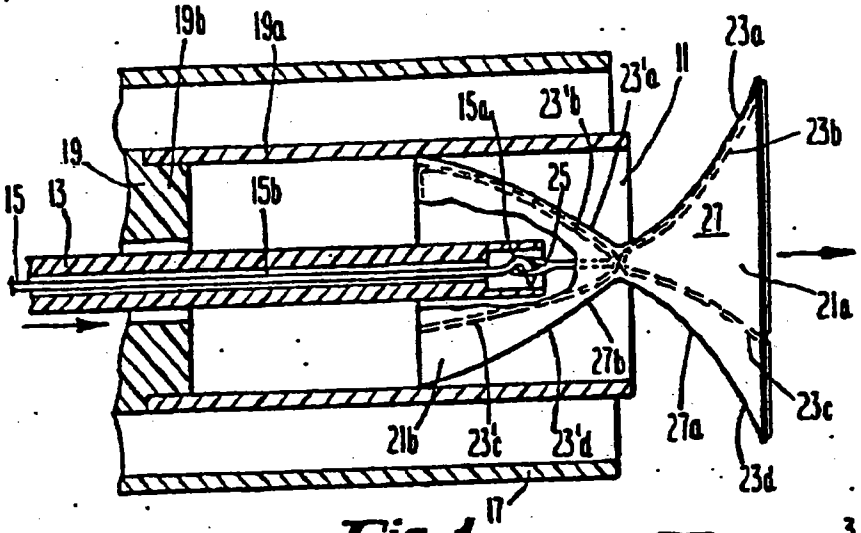

Fig. 1

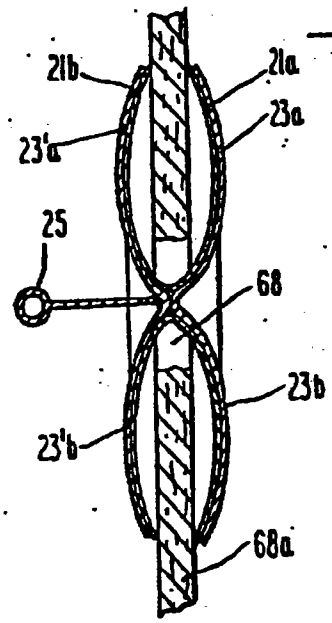

Fig. 5

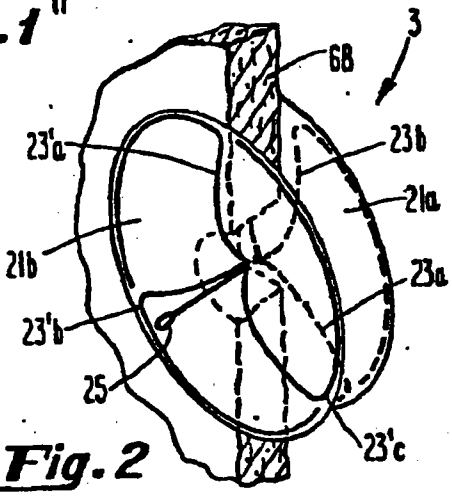

Fig. 2

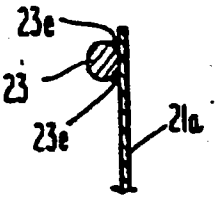

Fig. 4

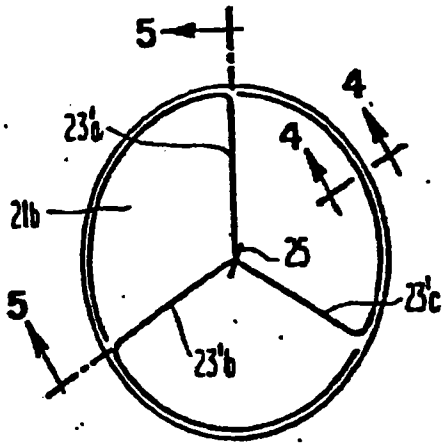

Fig. 3

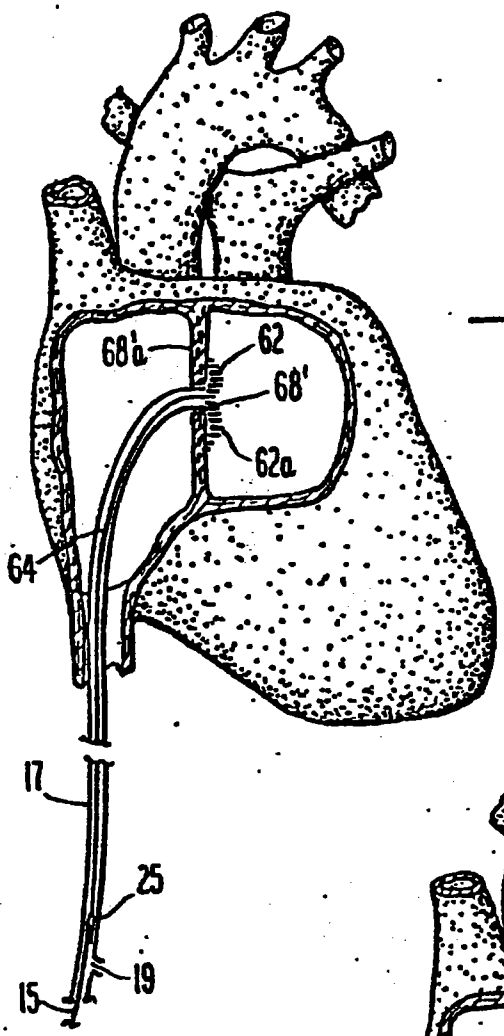

Fig. 6

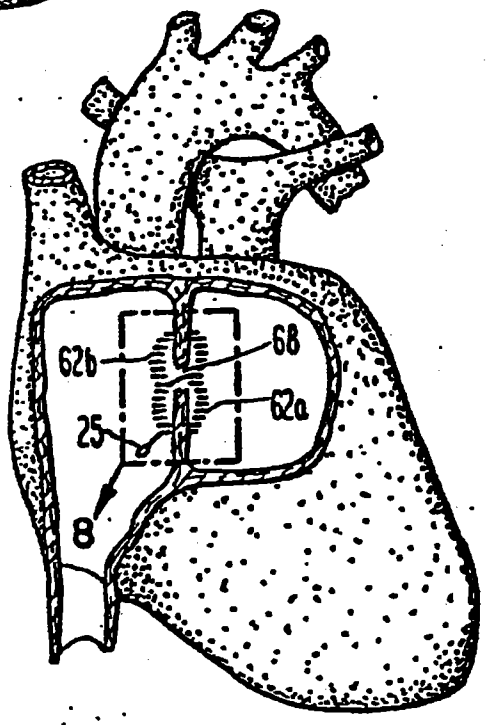

Fig. 7

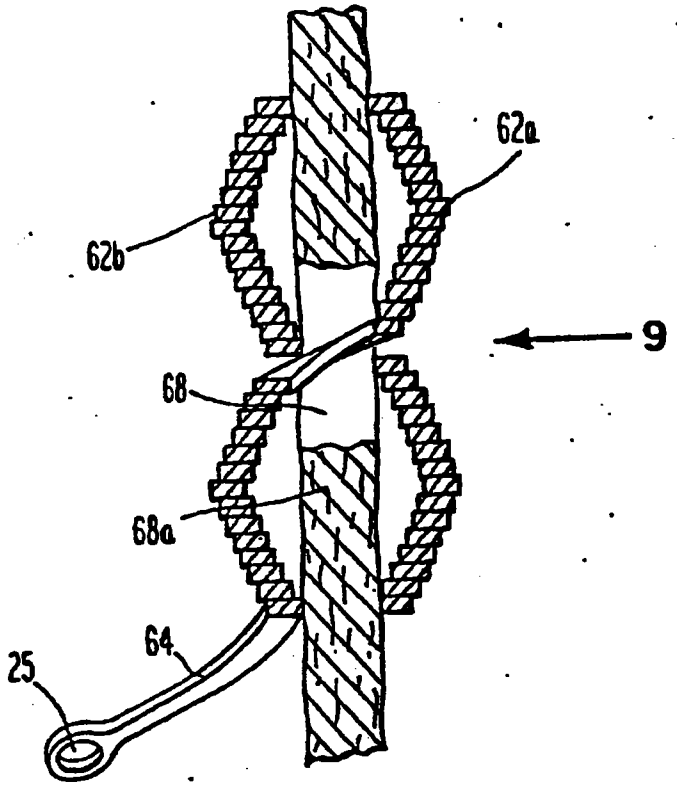

Fig. 8

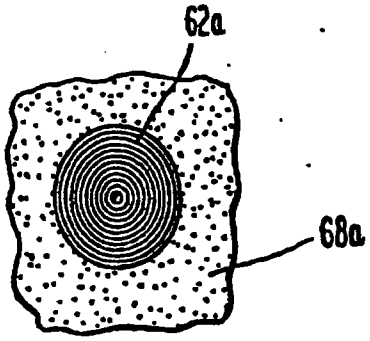

Fig. 9

APERTURE OCCLUSION DEVICE

FIELD OF THE INVENTION

The invention relates to devices and methods used to occlude (i.e. block blood flow through) an aperture within a body surface; specifically, it relates to devices and methods to occlude cardiovascular septal defects.

BACKGROUND OF THE INVENTION

It is often necessary to occlude a defect or an aperture within a body surface, such as a wall or membrane separating cavities within the body. A typical example is a congenital heart lesion called an atrial septal defect. This is a hole, between the two upper chambers of the heart, which must be closed.

King et al., U.S. Pat. No. 3,874,388, and Blake, U.S. Pat. No. 4,007,743 disclose a stainless steel apparatus for closing a shunt in the vascular system. The dual umbrella apparatus has six ribs which retain the umbrella in an open position. The King et al. apparatus has "barbs" at the ends of the ribs anchor onto the tissue surrounding the shunt. Alternatively, the barbs on the ribs of one umbrella may insert into holes on the ribs of the second umbrella, see FIG. 15A. The Blake apparatus has pivotally mounted struts which provide a flat surface to which a disk may be secured.

In "A New Percutaneous Vena Cava Filter", Cragg et al. disclose a filter composed of nitinol which when inserted into the inferior vena cava, traps emboli and clots. In the process of placing the filter, there is the threat of dislodging thrombi when the catheter or guide wire is advanced too far.

Lock et al., in *Circulation*, disclose a spring-loaded clamshell occluder of several sizes. The tension in the arms is manually controlled during delivery such that the arms of the distal umbrella, the one inserted first, are everted during placement, creating a cone.

The Rashkind occluder has two polyurethane foam disks mounted on surgical steel wire assemblies. The occluder is used to seal off the ductus arteriosus and is disclosed in *Circulation*, Vol. 75., page 583, *American Journal of Cardiology*, Vol. 64, page 218, and *Circulation*, Vol. 77, page 1068.

Devices currently used to occlude septal defects, including those indicated above, have been known to dislodge and embolize.

BRIEF DESCRIPTION OF THE INVENTION

The present invention comprises an aperture occlusion device which includes a wire having two configurations, an elongated configuration for passage through a catheter and through the aperture, and a second, preprogrammed, configuration. In the second configuration, two occlusion-forming wire segments oppose one another. These are adapted to be deployed on each side of the aperture to be occluded. A means for changing the wire from the elongated configuration to the preprogrammed configuration inside the body is further included. Typically, this may consist of a thermally responsive wire composition, the wire being preprogrammed so that at a certain temperature (body temperature for example), the wire, which is normally straight at other temperatures assumes a different ("preprogrammed") shape or configuration. Each occlusion-forming wire segment is adapted to press toward the opposing segment, thereby closing or occluding the aperture. Apertures or openings in other walls or membranes within the body or abnormally patent blood vessels may be similarly occluded.

In one embodiment, the occlusion-forming wire segments may comprise essentially flat helices, urged toward one another. In another embodiment, the wire may further include two foldable membranes, one associated with each occlusion-forming wire segment. The membranes are folded for transport through the catheter along with the wire. Upon conversion of the wire to its preprogrammed configuration, the membranes unfold onto a frame produced by the occlusion-forming wire segments, one on each side of the aperture.

Also included in the invention is a method for occluding an aperture by positioning a catheter at the distal side of the aperture and deploying a wire therethrough in an elongated configuration, (with the aid of a means for holding the wire) to the distal side of the aperture. Upon exiting the catheter, the wire converts to a preprogrammed configuration including an occlusion-forming wire segment on the distal side of the aperture. Upon continued deployment in the elongated configuration, the wire is permitted to assume the preprogrammed configuration including an opposing occlusion-forming wire segment on the proximal side of the aperture, with the two segments pressing toward one another. The wire is then disengaged from the means for holding the wire.

BRIEF DESCRIPTION OF THE FIGURES

FIG. 1 is a schematic cross-sectional view, during deployment, of one embodiment of the aperture occlusion device of the claimed invention;

FIG. 2 is a perspective view of another aperture occlusion device of the present invention in a fully deployed configuration;

FIG. 3 is planar view of the device shown in FIG. 2;

FIG. 4 is an enlarged cross-sectional view, in the plane 4—4 of FIG. 3;

FIG. 5 is a cross-sectional view, in plane 5—5, of the fully deployed aperture occlusion device shown in FIG. 3;

FIG. 6 is a perspective view of a heart, partially in cross-section, schematically showing an atrial septal defect and an occlusion device of the present invention partially deployed;

FIG. 7 is similar to FIG. 6, with the occlusion device fully deployed;

FIG. 8 is an enlarged cross-sectional view of the deployed aperture occlusion device shown in FIG. 7;

FIG. 9 is a planar view of the aperture occlusion device of FIG. 8.

DETAILED DESCRIPTION OF THE INVENTION

The invention includes devices and methods for occluding apertures in body surfaces, such as walls or membranes; the devices are adapted to be passed into the body through a catheter and through the aperture. Such apertures are openings, often congenital defects, connecting two cavities of the body. Fallopian tubes may also be occluded by using the devices and methods of the claimed invention. Cardiac septal defects are the type of apertures for which the preferred embodiments of the invention are designed. For example, the devices and methods of the present invention may be used to occlude a ventricular septal defect or an unwanted

vascular communication such as a patent ductus arteriosus.

An essential part of the present invention is a wire having two configurations, an elongated configuration or folded configuration for passage into the body through a catheter and through the aperture, and a preprogrammed configuration including occlusion-forming wire segments one on each side of the aperture. This wire also includes a means for causing it to change from the elongated configuration to the preprogrammed configuration inside the body. The device may also be combined with a catheter means for introducing the wire into the body. The catheter includes means for holding the wire, such as a release wire, while it is in the catheter and before it has been stimulated to convert to the preprogrammed configuration.

Preferably the wire is composed of a shape memory retentive material, such as nitinol, which causes the wire to change configurations, in response to a temperature change and which enables the wire to be activated at body temperature (having previously been at a different temperature) to assume a preprogrammed configuration. Spring steel may also serve this purpose. Furthermore, the wire must be biocompatible, and may be coated with Teflon, fibrin or endothelial cells, for example.

The occlusion forming wires may be associated with a foldable membrane, either by being embedded in the membrane or secured (by glue, stitches, staples or the like) to the surface thereof. In this embodiment, the membrane is transportable through a catheter in a folded configuration along with the wire. The occlusion-forming wires are adapted, upon converting to preprogrammed configuration, to unfold the membranes and to form a frame to support the membranes as domed or umbrella-shaped members on each side of the aperture. In another embodiment, the occlusion-forming wire is not attached to a membrane, and forms coiled helices, one on either side of the defect and urged toward each other.

Referring to FIG. 1, there is shown a partially deployed stage of one aperture occlusion device. As would be used for the occlusion of a septal defect, sheath 17 (a large catheter), after entering the body in a conventional manner, such as through a femoral vein, enters the heart via the inferior vena cava and is positioned on the distal side of an atrial septal defect in the body of the left atrium.

Release wire 15, including shaft 15*b* and knuckle 15*a*, device engaging catheter 13 and aperture occlusion device 27, all disposed within deployment catheter 19, are prepared as a unit prior to deployment through sheath 17 and introduced into the body either along with or later through sheath 17.

Aperture occlusion device 27 is composed of two biocompatible membranes 21*a* and 21*b*, each comprised of a thin polyurethane membrane film, for example. Preprogrammed shape memory retentive, wire ribs 23 and 23' are secured (and may be threaded, sewn or sandwiched) to each biocompatible membrane 21*a* and 21*b*. Eye 25, attached to wire ribs 23 and 23', extends from the center of aperture occlusion device 27 and engages knuckle 15*a* of release wire 15. One half of aperture occlusion device 27*b* is seen in the folded state; upon release from deployment catheter 19 and contact with body temperature, the membrane expands between the ribs, as shown by device half 27*a* with associated ribs 23. In FIG. 1, four wire ribs, 23*a–d* and 23'*a–d*, on each half of device 27, unfold, i.e. are converted from their elongated configuration to a second preprogrammed configuration, such as by a thermally stimulated shape change to a preprogrammed configuration, which urges the wire ribs outwardly, to expand and release. For this purpose, ribs 23*a–d* and 23'*a–d* are composed of a thermally responsive shape, shape memory retentive material, such as nitinol.

For transport to the site of deployment, the unit including release wire 15, device engaging catheter 13 and aperture occlusion device 27 are channeled into pod 11 of deployment catheter 19. Deployment catheter 19 includes an inner plastic portion 19*b* integrally connected to outer metal portion 19*a*. Release wire 15, device engaging catheter 13 and aperture occlusion device 27 are retained together and folded in deployment catheter 19. In practice, device 27 may be deployed without the use of deployment catheter 19, so long as sheath 17 is in a cold environment thus prohibiting device 27 from forming the preprogrammed shape.

In use, the assembly including release wire 15, device engaging catheter 13, aperture occlusion device 27 and deployment catheter 19 are passed through sheath 17 until the distal half of device 27 is disposed on the distal side of the septal defect (i.e. "aperture") to be occluded. Device engaging catheter 13, release wire 15, and aperture occlusion device 27 are maintained in place on the distal side of the defect while sheath 17 is retracted back through the defect to the proximal side thereof. Device engaging catheter 13 and release wire 15 are advanced freeing 27*a* to expand to preprogrammed shape. This enables a thermally stimulated shape change to the preprogrammed deployed configuration of ribs 23*a–d*. One-half of aperture occlusion device, 27*a*, is thus deployed on the distal side of the septal defect.

Coincident with the pull-back movement of deployment catheter 19 either in the preceding step or in the following step, sheath 17 is also retracted away from the aperture to be occluded.

Aperture occlusion device 27 is then pulled taut against the defect such that four wire ribs 23*a–d* expand and contact the heart tissue around the defect. Optionally, sheath 17 is then pulled back further away from the proximal side of the defect (if that had not been done earlier), and deployment catheter 19 is retracted leaving device engaging catheter 13, release wire 15, and aperture occlusion device 27 in place and thus exposing aperture occlusion device half 27*b* on the proximal side of the defect, at which point the second half 27*b* of device 27 is deployed.

Once aperture occlusion device 27 is fully deployed, as seen in FIGS. 2-5, knuckle 15*a* is disengaged from eye 25 of aperture occlusion device 27, by retracting catheter 13 slightly from eye 25. The assembly including deployment catheter 19, device engaging catheter 13 and release wire 15 are then retracted from sheath 17. Finally, sheath 17 is also retracted from the body.

FIG. 2 depicts a perspective view of an aperture occlusion device, with 3 ribs, like that seen in FIG. 1, but fully deployed to occlude a defect or aperture 68 in wall 68*a*. Membranes 21*a* and 21*b* are supported by wire ribs 23*a–c* and 23'*a–c* respectively, which urge the membranes toward each other and connect the membranes with eye 25.

As seen in FIG. 3, membrane 21*a* is attached to three wire ribs 23*a*, *b* and *c* extending circumferentially then curving and radially extending to the center of membrane 21a. Ribs 23*a–c* attach at the center of membrane

21a and connect the pair to each other and to eye 25 which attaches to a release wire, not shown. Ribs 23a–c, upon thermal triggering of the memory retentive properties of the rib material (preferably nitinol), support and maintain the shape of membrane 21a. Membrane 21b is similarly retained by ribs 23'a–c.

FIG. 4 is a cross-section through plane 4—4 of FIG. 3. As depicted therein, membrane 21a is secured to rib 23a by glue 23e. Stitches, staples or the like may also be used to affix membrane 21a to rib 23a. Other configurations of ribs 23a, b, c may also be used.

FIG. 5 illustrates a cross-section along plane 5—5 of the aperture occlusion device of FIG. 3. Membranes 21a and 21b occlude aperture 68 in wall 68a, and are supported by wire ribs, 23a, b and 23'a, b, which urge the membranes toward each other and connect the membranes with eye 25.

FIG. 6 depicts septal defect 68' with a double helix occlusion device 62 partially deployed. Device 62 is introduced as a straight wire 64 through the assembly including, device engaging catheter 13 (like that shown in FIG. 1, but not shown in FIG. 6 due to limited space available), release wire 15 and sheath 17. Sheath 17 is diametrically larger than device engaging catheter 13 to allow passage of device engaging catheter 13 therethrough. As with the assembly shown in and described with respect to FIG. 1, the assembly of release wire 15, device engaging catheter 13, wire 64 and sheath 17 are introduced through a large vein to and through the defect to be occluded. Sheath 17 optionally may be stopped short of defect 68' and may be withdrawn with device engaging catheter 13, as described, or independently of catheter 13.

Helix 62a is formed on the distal side of defect 68', preferably by the coiling of wire 64, nitinol for example, in response to a temperature change, upon body temperature contact or by retraction of spring steel into its "relaxed" (preprogrammed) configuration. A plurality of coils of progressively smaller diameter are formed, finally contacting the periphery of atrial wall 68a' surrounding defect 68' on the distal side thereof; each such coil of wire 64 contacts the previously formed coil above and below defect 68', such that helix 62a is deployed from the outside in, (relative to defect 68), until helix 62a is formed (as seen in FIG. 6).

The aperture occlusion device of FIG. 6 after deployment into the left atrium is seen in FIG. 9. The concentric circles are the result of the coiling of wire 64 (in this case from a very small starting circumference out) and also contacting the previously formed coil above and below defect 68', this time on the proximal side thereof.

After deploying helix 62a on the distal side of defect 68, sheath 17, device engaging catheter 13, release wire 15, and wire 64 are withdrawn equally and together to bring helix 62a into firm contact with the septal surface. As tension is maintained on wire 64 via release wire 15, sheath 17 is withdrawn over wire 64 and release wire 15, thereby exposing a length of wire 64 on the proximal side of the defect. Tension on wire 64 is then slowly reduced by advancing release wire 15 and sheath 17 equally and together. Wire 64 begins coiling at or near septal surface below defect 68. By progressively reducing tension on wire 64 (by repetitively withdrawing sheath 17 over release wire 15 and advancing sheath 17 and release wire 15 equally and together), successive coils are formed, each moving outward beyond the previously formed coil. Thus, helix 62b is formed from the inside out, until helix 62b is fully deployed as seen in FIGS. 7 and 8. Eye 25 is then disengaged from the release wire 15 (not shown), and the remaining apparatus is removed from the body as described with respect to FIG. 1.

In those embodiments dependent upon a thermally responsive change (such as with nitinol) as the means for effecting device deployment, it is desirable prior to deployment to continuously infuse a biocompatible fluid (such as normal saline) which is substantially below body temperature (for example at room temperature) through side port 19 of sheath 17 to maintain a thermal environment within sheath 17, that is below the transition temperature of the thermally responsive wire 64. This assures that wire 64 will not assume its programmed shape until it exits sheath 17.

Furthermore, the programmed deployed configuration of the double helix coil (in the embodiment of FIGS. 6–9) may preferably include shaping to urge the outermost coils of helices 62a and 62b inward toward the septal surface (and one another) to provide an increased frictional force between the helices and their respective septal surfaces.

By way of general description of the method of this invention, the device of the present invention may be used in a method of occluding an aperture within a body surface. A catheter, which can accommodate a wire in an elongated or folded configuration (optionally with an associated membrane), is introduced through a body member such as a femoral vein, deployed, for example, into the heart through the inferior vena cava and manipulated into position on the distal side of the aperture where the wire assumes its preprogrammed configuration including an occlusion-forming wire segment urged toward the aperture on the distal side of the septal defect. Withdrawing the catheter partially over the wire allows a substantial length of the wire to be exposed on the near side of the defect. Upon further deployment, the wire assumes a preprogrammed configuration including an occlusion-forming wire segment urged toward the aperture on the proximal side of the aperture. The wire is then disengaged from the means for holding it.

The device and method of this invention are believed to be particularly well adapted to occlude both atrial and ventricular septal defects, as well as other cardiovascular openings, such as a patent ductus arteriosus. The device (modified for tubal rather than aperture occlusion) is also well suited for use in occluding fallopian tubes.

In the embodiments disclosed, the finished structure comprises two connected occlusion-forming wire segments, disposed on opposite sides of an aperture, each formed of a wire resulting in helices, or domed members (with membranes attached to a wire frame), urged toward one another.

While this invention has been disclosed with reference to specific embodiments, it is apparent that other embodiments and equivalent variations of this invention may be devised by those skilled in the art without departing from the true spirit and scope of this invention. The appended claims are intended to be construed to include all such embodiments and equivalent variations.

What is claimed is:

1. A device adapted to occlude an aperture within a body surface, and adapted to be passed into said body, through a catheter and through said aperture, said device comprising a wire having two configurations, an elongated configuration for passage through said cathe-

ter and through said aperture, and a preprogrammed configuration which includes occlusion-forming wire segments one on each side of said aperture urged toward one another and means for causing said wire to change from said elongated configuration to said preprogrammed configuration inside said body, said means being a temperature responsive material of construction of said wire, by which said wire is activated at body temperature, to assume said preprogrammed configuration.

2. A device of claim 1 wherein said wire is combined with a catheter means for introducing said wire into said body, said catheter means also includes means for holding said wire, while it is in said catheter, at a temperature at which said wire does not tend to assume said preprogrammed configuration.

3. A device of claim 1 wherein said occlusion-forming segments each comprise helical coils urged toward one another.

4. A device of claim 1 wherein said wire further includes two foldable membranes, one associated with said first occlusion-forming wire segment and the other associated with said second occlusion-forming wire segment, said membranes in folded configuration being transportable through a catheter along with said wire, said wire adapted upon converting from said elongated configuration to said preprogrammed configuration to unfold said membranes and to form a frame supporting said membranes as essentially planar members, one disposed on each side of said aperture, and urged toward one another, wherein said means for causing a change in configuration is a thermally responsive material of construction.

5. A device according to claim 4 wherein said wire is secured to said membranes of said occlusion-forming wire segments.

6. A device according to claim 1, wherein said wire consists of nitinol.

7. A device according to claim 1, wherein said wire is biocompatible.

8. A device according to claim 1, wherein said wire is coated to enhance biocompatibility.

9. A device adapted to occlude an aperture within a body surface, and adapted to be passed into said body, through a catheter and through said aperture, said device comprising a wire having two configurations, an elongated configuration for passage through said catheter and through said aperture, and a preprogrammed configuration which includes occlusion-forming wire segments one on each side of said aperture, and means for causing said wire to change from said elongated configuration to said preprogrammed configuration inside said body, wherein said occlusion forming segments each comprise helical coils urged toward one another.

10. A device according to claim 9, wherein said wire consists of spring steel.

11. A method for occluding an aperture within a body surface by positioning the end of a catheter at the distal side of the aperture, deploying a wire of temperature responsive material of construction in an elongated configuration through said catheter to the distal side of said aperture with the aid of a means for holding said wire, permitting the wire exposed thereby to assume a preprogrammed configuration, including an occlusion-forming wire segment on the distal side of said aperture, and urged toward said aperture, withdrawing the end of said catheter through said aperture and deploying an additional length of said wire in an elongated configuration to be exposed on the proximal side of said aperture, whereupon said continued deployment, said wire is permitted to assume a preprogrammed configuration, including an opposing occlusion-forming wire segment urged toward said aperture on the proximal side of the aperture, and disengaging the wire from the means for holding said wire.

12. A method as recited in claim 11, wherein said defect is a atrial septal defect.

13. A method as recited in claim 11, wherein said defect is a ventricular septal defect.

14. A method as recited in claim 11, wherein said defect is a patent ductus arteriosus.

* * * * *

EXHIBIT G

Address: ASSISTANT COMMISSIONER FOR PATENTS
Washington, D.C. 20231

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
90/006,043	JUNE 25, 2001	5,108,420	000365-00002

BLANK ROME COMISKY & MCCAULEY, LLP
900 17TH STREET, N. W., SUITE 1000
WASHINGTON, DC 20006

EXAMINER
THALER, M.

ART UNIT	PAPER
3731	23

DATE MAILED: FEBRUARY 5, 2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev.3-98)

U.S. DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

CONTROL NUMBER	FILING DATE	PATENT UNDER REEXAMINATION	ATTORNEY DOCKET NO.

EXAMINER

ART UNIT	PAPER NUMBER

DATE MAILED:

OFFICE ACTION IN REEXAMINATION

☒ Responsive to the communication(s) filed on DEC. 2, 2002. ☒ This action is made FINAL.

A shortened statutory period for response to this action is set to expire ONE month(s) from the date of this letter. Failure to respond within the period for response will cause termination of the proceeding and issuance of a reexamination certificate in accordance with this action. 37 CFR 1.550(d). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).**

PART I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Information Disclosure Citation, PTO-1449.
3. ☐ Notice of Informal Patent Drawing, PTO-948.
4. ☐ _____.

PART II SUMMARY OF ACTION:

1. ☒ Claims 1-80 are subject to reexamination.
1. ☐ Claims _____ are not subject to reexamination.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are confirmed.
4. ☐ Claims _____ are patentable.
5. ☒ Claims 1-80 are rejected.
6. ☐ Claims _____ are objected to.
7. ☐ The formal drawings filed on _____ are acceptable.
8. ☒ The drawing correction request filed on DEC. 2, 2002 is ☒ approved, ☐ disapproved.
9. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received, ☐ not been received, ☐ been filed in Serial No. _____ filed on _____.
10. ☐ Since the proceeding appears to be in condition for issuance of a reexamination certificate except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 435 O.G. 213.
11. ☐ Other

cc: Requester

PTOL-466 (2-90)

The amendment filed Dec. 2, 2002 does not comply with 37 CFR 1.530(d)(1), (d)(2) and (f) since the clean version does not show changes made to the specification relative to the patent with appropriate markings (bracketing and underlining). Further, claims 28, 31 and 32 are not completely underlined as they should be since they are new relative to the patent. Any future response should correct these matters.

The drawing correction request filed on Dec. 2, 2002 is approved.

Claims 18 and 22-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 9 is limited to the embodiment of figures 6-9 since the embodiment of figures 1-5 fails to include helical coils as defined in claim 9, line 12. The original disclosure fails to disclose a membrane in the embodiment of figures 6-9. In fact, it is unclear how one could even include a membrane in this embodiment due to the manner in which helixes 62a and 62b are deployed as explained in col.5, lines 38-68. Thus, there is no basis in the original disclosure for the membrane defined in claims 18, 22, 24, 29 and 33, each of which depends from a claim (claim 9) which is limited to the embodiment of figures 6-9. Further, claims 23 and 25, which

also depend from claim 9, each define more than one wire. The only embodiments which include more than one wire are the embodiments of figures 1-5. The original disclosure fails to disclose a plurality of wires in the embodiment of figures 6-9. Thus, there is no basis in the original disclosure for the plurality of wires defined in claims 23 and 25, each of which depends from a claim (claim 9) which is limited to the embodiment of figures 6-9. Claim 28 is similarly defective since it includes both a plurality of wires and helical coils.

Claims 1-5, 9, 11, 14, 15, 18, 19, 21, 23-25, 27-31, 33-39, 41-44, 46-64, 66-68, 70-75, 77, 78 and 80 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Munster (Germany 233,303). Munster shows a device 1 (either the embodiment of figure 1 or the embodiment of figure 2) to occlude an aperture within a body surface comprising a wire having an elongated configuration (the stretched form of the wire while it is in catheter 4 as seen in figure 3, for example and described on page 8, paragraph f and page 12, lines 3-9) and a preprogrammed configuration which includes occlusion-forming wire segments, one on each side of the aperture, urged toward one another. The wire segments have been "urged toward one another" since they move radially outward and longitudinally toward each other as they emerge from the catheter as described in paragraphs g and h on pages 8 and 9, and page 12,

lines 10-20. The wire segments are inherently "occlusion-forming" since they are urged toward each other, as described above, until they come to rest against the wall of the aorta on one side and the tissue around the duct on the other, pulmonary side as indicated on page 9, lines 1-10. Although the formation of the occlusion may be supplemented by the swelling plastic or the balloon described on page 9, paragraph j, the wire segments themselves are inherently "occlusion-forming" since they come to rest against the tissue on both sides of the aperture and therefore form a blockage for the blood. Even if this blockage is not perfect, i.e. even if some leakage occurs, the wire segments are still "occlusion-forming" since the occlusion is still formed even though it is not perfect. In any event, assuming *arguendo* that the Munster wire segments of occluding device 1 are not "occlusion-forming" because they do not press against the tissue with sufficient force to form an occlusion, these wire segments, with no modification, when placed on opposite sides of an anatomical member having a slightly longer aperture, would form an occlusion since they would press against the tissue with greater force since they would be farther away from their at rest, relaxed position. Alternatively, the Munster wire segments are obviously "occlusion-forming" for the reasons set forth above. As to claims 4, 18, 24, 33, 35, 41, 55, 67, 67, 75 and 78, Munster discloses foldable membranes (opposite end portions of the balloon described on page 10, lines 23-25). It is

clear that the Munster balloon is long enough such that it extends as far as the wire segments on opposite sides of the aperture (at end portions 2 and 3 of the occluding device 1) so that the end portions of the balloon are "associated with" the wire segments on opposite sides of the aperture, as claimed. This is because the central portion of the balloon possesses a narrowed waist which is located around the central bridge or narrowed waist 5 of the occluding device 1, leaving the end portions of the balloon (on opposites ends of the narrowed waist) located at end portions 2 and 3 of the occluding device 1. As to claims 37 and 43 and 54, the Munster domed member formed by the membrane and wire segments is outwardly convex since the outer edge or periphery of the domed member is outwardly convex. In other words, the outer edge or periphery is outwardly convex in the same manner that the outer edge or periphery of a disc is outwardly convex. As to claim 48, the Munster wire segment in figure 1 is configured to form a circular periphery (at the extreme left and right ends of the device) with a center, the wire segment extending from the center (at central bridge 5) to the periphery (in a helical fashion). Although the central bridge 5 is not precisely at the geometric center point of the circular periphery, the term "center" is considered to be the general central area of the circular periphery. The central bridge 5 is located at the center in this sense. Note that wire ribs 23a-d and 23'a-d of the Marks patent do

not extend completely to the geometric center point of the circular periphery as seen in amended figures 1 and 5, for example. Rather, the axial rod which supports eye 25 is at the exact center while the wire ribs 23a-d and 23'a-d are radially spaced from the exact center and are located around the axial rod. As to claims 50 and 51, the wire segments shown in figure 2 of Munster extend generally radially and along a radius as claimed. As to claims 52 and 53, each of the Munster wire segments in figure 1 extends from the center (helically) and also curves and extends circumferentially to the periphery at the outermost winding of the helix. As to claim 60, the figure 1 Munster wire segments at the outermost periphery are inherently configured to engage and press against a body which is thick enough near the outermost periphery such that the body surface engages the wire segments at the outermost periphery.

Claims 6-8, 10, 12, 13, 16, 17, 20, 22, 26, 32, 40, 45 and 65, 69, 76 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Munster (Germany 233,303). As to claims 6, 16, 20, 26, 32, 40 and 45, Munster fails to show nitinol as the temperature responsive material. However, nitinol is well known in the art as being a material which is very responsive to temperature change. It would have been obvious to use nitinol as the Munster temperature responsive material for this reason. As to claims 10, 20, 26 and 32, Munster fails to show spring steel as the shape memory retentive material. However, spring steel is well known in

the art as being a material which returns to its shape effectively. It would have been obvious to use as spring steel the Munster shape memory retentive material for this reason. As to claims 7 and 8, including a biocompatible coating on the Munster wire in order to make it more compatible with the body would have been obvious since it is well known in this art to include such a coating on implantable members for this reason. As to claims 12 and 13, using the Munster occluding device on an atrial septal defect or a ventricular septal defect would have been obvious particularly since it is well known in this art that such defects may be corrected by an occluding device. As to claims 65, 69, 76 and 79, Munster fails to show stitching. However, using stitching to secure the membrane (the balloon described on page 10, lines 23-25) to the wire in order to insure that it does not become detached would have been obvious since stitching in general is a well known securing means in this art.

The declarations filed on June 20, 2002 and Dec. 2, 2002 under 37 CFR 1.131 are sufficient to overcome the Kamiya et al. (5,192,301) reference.

Patent Owner's arguments filed Dec. 2, 2002 have been fully considered but they are not persuasive. The argument on pages 9-11 of the response that the original disclosure of the Marks patent indicates that the wire ribs 23a-c, 23'a-c in the embodiments of figures 1-5 are "helical coils" is not well taken. First, claim 9

requires the wire (singular) to include occlusion-forming wire segments one (singular) on each side of the aperture, wherein the occlusion-forming segments each (singular) comprise "helical coils". Claim 28 has a similar limitation wherein the occlusion-forming wire segments each comprise helical coils. Each of the wire ribs 23a-c, 23'a-c does not form "coils" since each wire rib extends circumferentially less than 360 degrees and thus does not even form one coil. For example, if the claimed "wire" is considered to be wire 23a, 23'a, then occlusion-forming wire segment 23a extends circumferentially less than 360 degrees and thus does not even form one coil, much less a plurality of coils. Second, a helix (even as defined by the definition supplied by Patent Owner) requires the curve to lie on a cylinder or cone and cut the elements at a constant angle. Assuming that the variations in septal thickness (described in paragraphs 9 and 10 in the declaration of Lloyd A. Marks under 37 C.F.R. 1.132) result in the circumferential portions of the wire not lying flat but rather varying with the variations in septal thickness (paragraph 10 of the declaration), then there is no evidence that the angle of the wire ribs would necessarily be at a constant angle as required. In other words, there is no evidence that a single wire rib would necessarily lie at a constant angle from one end of the circumferential portion of the rib to the other. Also, there is no evidence that each of the wire ribs would necessarily lie at the

same angle of the other ribs. Third, all indications from the specification and drawings are that the circumferential portions of the wire ribs lie in the same plane both while they are within the catheter and while they are outside of the catheter as seen in figure 1, for example. In figure 1, the left portion of the occlusion device is within the catheter. The extreme left end of this left portion of the occlusion device is shown as a vertical line which indicates that the circumferential portions of the wires lie in the same plane (defined by the vertical line). Even if the circumferential portions of the wires overlap one another in the circumferential direction, this does not indicate that they are helical. Each circumferential portion could bend slightly where it meets the radial portion while still remaining planar. Further, there is no indication from the Marks patent that the circumferential, arc-shaped segment of wire portion 23'a, for example, when compressed within the catheter, extends at least 720 degrees to form a plurality of coils. In any event, claim 9 requires the wire to include helical coils when it is in the "preprogrammed configuration which includes occlusion-forming wire segments one on each side of said aperture" also noting "wherein said occlusion forming segments each comprise helical coils urged toward one another" (underlining added). Thus, even assuming *arguendo* that the wire in the figure 1-4 embodiment of Marks is helical when it is within the catheter (which it is not), it is not

helical when it is in the preprogrammed configuration (which includes occlusion-forming wire segments one on each side of said aperture) which is the configuration claimed to be helical. Fourth, in col. 2, lines 3-7 of the Marks patent, it is stated, "In one embodiment, the occlusion-forming wire segments may comprise essentially flat helices, urged toward one another. In another embodiment, the wire may further include two foldable membranes..." (underlining added). This indicates that one embodiment includes helices while the other does not. Also, in col. 3, lines 37-40, it is stated, "In another embodiment, the occlusion-forming wire is not attached to a membrane, and forms coiled helices, one on either side of the defect and urged toward each other.". This indicates that only one embodiment (not both embodiments) forms coiled helices.

The arguments on pages 12-18 of the June 20, 2002 response and pages 11-19 of the Dec. 2, 2002 response regarding Munster are not well taken. Patent Owner alleges on page 14 of the June 20, 2002 response and page 15-17 of the Dec. 2, 2002 response that the wire ends 2, 3 of Munster are not occluding elements since occlusion is accomplished only by the swelling of the central bridge 5 by plastic foam on a balloon or by textile fibers or bristles. This allegation is simply incorrect. Textile fibers or bristles 9 extend all along the wire ends 2, 3 as seen in figure 1 of Munster. Thus, the wire ends 2, 3, which support the bristles, act as

occluding elements. Note that the wire ribs 23a-c, 23'a-c of the Marks patent are considered to be occluding elements even though they merely support the membranes 21a, 21b which form the occlusion in the embodiments of figures 1-5. Patent Owner argued in the interview held April 11, 2002 and reiterates on pages 16-18 of the June 20, 2002 response that the phrase "preprogrammed configuration which includes occlusion-forming wire segments one on each side urged toward one another" in the claims requires the wire segments to be pressing against one another without any tissue therebetween. Specifically, Patent Owner argues on page 16 that the "preprogrammed configuration" of the wire in Marks patent is the condition of the occluding device when it is manufactured (and not within the human body). It was argued that in this condition, as manufactured, the wire segments press against one another with no tissue therebetween and are thus "urged toward one another". It was then argued that the wire segments of Munster are separated when they are in the "preprogrammed configuration" and thus are not pressing directly against one another and thus are not "urged toward one another". There are several problems with this interpretation. First, as to the question of what the "preprogrammed configuration" is, the Marks patent makes it crystal clear what the "preprogrammed configuration" is. Both the specification and claims indicate that the "preprogrammed configuration" of the wire is the configuration of the wire while

it is within the body (and not when it is manufactured but prior to placement within the body). For example, claim 1 defines the "preprogrammed configuration" of the wire to be the configuration in which the wire segments are located on each side of the aperture (and thus within the body). Also, similar language appears in col. 3, lines 3-8 of the specification. There in no indication from the Marks disclosure that the wire segments actually touch one another when no tissue is therebetween. The disclosure is silent on this point. In any event, the Munster wire segments are clearly urged toward one another since they move radially outward and longitudinally toward each other as they emerge from the catheter as described in paragraphs g and h on pages 8 and 9, and page 12, lines 10-20. Thus, there is a biasing force which urges the Munster wire segments toward one another. Further, the wire segments are urged toward each other, as described above, until they come to rest against the wall of the aorta on one side and the tissue around the duct on the other, pulmonary side as indicated on page 9, lines 1-10. Thus, even if the Munster wire segments, when they come to rest against the tissue, do not press against the tissue even in the slightest amount as they touch it (which is extremely unlikely as set forth below), they still have been "urged toward each other" as they moved toward each other. Claims 1-61 and 72-80 do not require the wire segments to be (in the present) actively pressing against the tissue and urging toward one another.

However, assuming *arguendo* that the claims require this, it certainly would be very difficult, if not impossible, to size the Munster occluding member so that the wire segments, when they come to rest against the tissue, would not press against the tissue even an infinitesimal amount (i.e. with exactly zero force). Note that the amount "urged" is not claimed. However, even if this unlikely event happened, the Munster wire segments, with no modification, when placed on opposite sides of an anatomical member having a slightly longer aperture, would inherently press against the tissue since they would be away from their at rest, relaxed position and thus be "urged toward each other" even in this specific interpretation of the phrase. Also, there is no teaching in Munster that the wire segments, as they are intended to operate, do not press against the tissue. It certainly would have been obvious to size them so that they press against tissue when implanted in the body in order to insure that they come to rest against tissue as intended.

As to the argument in the paragraph bridging pages 15 and 16 of the June 20, 2002 response, first, a comparison of figures 1 and 3 of Munster is not particularly relevant since these figures denote different embodiments. Second, a comparison of figures 3 and 4 (which show the same occluding member inside the catheter in figure 3 and outside the catheter in figure 4) show that arms 8 move longitudinally toward each other as the occluding member is

deployed and thus are urged toward each other during this movement.

As to the argument on page 19 of the Dec. 2, 2002 response regarding claim 2, Munster discloses the claimed means for holding the wire, which includes holding wire 7.

THIS ACTION IS MADE FINAL.

A shortened statutory period for response to this action is set to expire one month from the mailing date of this action.

Extensions of time under 37 CFR 1.136(a) do not apply in reexamination proceedings. The provisions of 37 CFR 1.136 apply only to "an applicant" and not to parties in a reexamination proceeding. Further, in 35 U.S.C. 305 and in 37 CFR 1.550(a), it is required that reexamination proceedings "will be conducted with special dispatch within the Office."

Extensions of time in reexamination proceedings are provided for in 37 CFR 1.550(c). A request for extension of time must be filed on or before the day on which a response to this action is due. The mere filing of a request will not effect any extension of time. An extension of time will be granted only for sufficient cause, and for a reasonable time specified.

The filing of a timely first response to this final rejection will be construed as including a request to extend the shortened statutory period for an additional month, which will be granted even if previous extensions have been granted. In no event however, will the statutory period for response expire later than

SIX MONTHS from the mailing date of the final action. See MPEP § 2265.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703)308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht
January 28, 2003

MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731

David Reip
Primary Examiner
(conferee)

Kevin Truong
Primary Examiner
(conferee)

EXHIBIT H

Docket No. 000365-00002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE REEXAMINATION OF U.S. PATENT OF: LLOYD A. MARKS GAU: 3731

PATENT NO: 5,108,420 EXAMINER: M. Thaler

REEXAM CONTROL NO.: 90/006,043

ISSUED: April 28, 1992

FOR: APERTURE OCCLUSION DEVICE

RECEIVED
APR 18 2003
TECHNOLOGY CENTER R3700

NOTICE OF APPEAL

COMMISSIONER FOR PATENTS
BOX REEXAM
WASHINGTON, D.C. 20231

SIR:
The patent owner hereby appeals to the Board of Appeals from the decision dated February 5, 2003

The items checked below are appropriate:

☒ A petition for Extension of Time Under 37 C.F.R. §1.550(c) was filed for one month.

☒ A timely response to the final rejection was filed on April 4, 2003.

☐ A petition for Extension of Time for filing the Notice of Appeal is attached, together with the $ petition fee.

Fee: $320.00

☒ Is Enclosed

☐ Charge to Deposit Account No. 23-2185 (an additional copy of this notice is enclosed herewith).

☒ Please charge any additional fees or credit any overpayment of fees required for filing the Notice of Appeal to Deposit Account No. 23-2185. A duplicate copy of this Notice is enclosed.

☒ If this notice is not considered timely filed by the U.S. Patent and Trademark Office, then a petition is hereby made under 37 C.F.R. §1.550(c) for any necessary extension of time.

Respectfully Submitted,

BLANK ROME LLP

Michael D. White
Attorney for Patent Owner
Registration No. 32,795

THE FARRAGUT BUILDING
SUITE 1000
900 17TH STREET, NW
WASHINGTON, DC 20006
TEL (202) 530-7400
FAX (202) 463-6915

Date: April 17, 2003

RECEIVED
APR 17 2003
TECHNOLOGY CENTER 3700

000365.00002/35328406v1

Docket No. 000365-00002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE REEXAMINATION OF U.S. PATENT OF:	LLOYD A. MARKS	GAU:	3731
PATENT NO:	5,108,420	EXAMINER:	M. Thaler
REEXAM CONTROL NO.:	90/006,043		
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Respectfully Submitted,

BLANK ROME LLP

Michael D. White
Attorney for Patent Owner
Registration No. 32,795

THE FARRAGUT BUILDING
SUITE 1000
900 17TH STREET, NW
WASHINGTON, DC 20006
TEL (202) 530-7400
FAX (202) 463-6915

Date: April 17, 2003

EXHIBIT I

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

NITINOL MEDICAL LABORITORIES, INC. ET AL. Plaintiffs,	)	
v.	)	C.A. No. 98-12506-NG
AGA MEDICAL CORPORATION, Defendant.	)	

GERTNER, D.J.:

ORDER OF DISMISSAL
December 1, 2003

The Defendant in this case moves to dismiss the Plaintiffs' Complaint in its letter dated September 30, 2003. [Document # 127]. The Defendant's request is GRANTED. The case is thus DISMISSED without prejudice.

SO ORDERED.

Dated: December 1, 2003

s/Nancy Gertner
NANCY GERTNER, U.S.D.J.

EXHIBIT J

Stab/Drug.

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 38

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte LLOYD MARKS

Appeal No. 2004-1453
Reexamination Control No. 90/006,043

HEARD: July 15, 2004

Before COHEN, STAAB, and NASE, Administrative Patent Judges.
STAAB, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on an appeal from the examiner's final rejection of claims 1-80 in this patentee requested reexamination proceeding for U.S. Patent No. 5,108,420. Two proposed amendments have been submitted subsequent to the final rejection. The first amendment after final (Paper No. 26) was refused entry. The second amendment after final (Paper No. 28) was entered, and as a consequence claims 18 and 22-33 were canceled. In addition, upon

further review the examiner has withdrawn the rejection as to dependent claims 65, 69, 76 and 79, and indicated that these claims would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claim. Accordingly, the appeal as to claims 65, 69, 76 and 79 is dismissed, leaving for our consideration only the standing rejections of claims 1-17, 19-21, 34-64, 66-68, 70-75, 77, 78 and 80. Of these remaining claims, claims 1-14 correspond to claims 1-14 of the patent, and claims 15-17, 19-21, 34-64, 66-68, 70-75, 77, 78 and 80 are new claims added during prosecution.

The Invention

Appellant's invention relates to devices and methods used to occlude (i.e., block blood flow through) an aperture within a body surface of a living body. More specifically, the invention "relates to devices and methods to occlude cardiovascular septal defects" (column 1, lines 7-8). As further explained at column 2, line 59, through column 3, line 2, the inventive devices

> are adapted to be passed into the body through a catheter and through the aperture. Such apertures are openings, often congenital defects, connecting two cavities of the body. . . . Cardiac septal defects are the type of apertures for which the preferred embodiments of the invention are designed. For example, the devices and methods of the present invention may be used to occlude a ventricular septal defect or an unwanted vascular communication such as a patent ductus arteriosus.

The paragraph spanning columns 1 and 2 describes the basic features of the inventive device as follows:

> The present invention comprises an aperture occlusion device which includes a wire having two configurations, an elongated configuration for passage through a catheter and through the aperture, and a second, preprogrammed, configuration. In the second configuration, two occlusion-forming wire segments oppose one another. These are adapted to be deployed on each side of the aperture to be occluded. A means for changing the wire from the elongated configuration to the preprogrammed configuration inside the body is further included. Typically, this may consist of a thermally responsive wire composition, the wire being preprogrammed so that at a certain temperature (body temperature for example), the wire, which is normally straight at other temperatures assumes a different ("preprogrammed") shape or configuration. Each occlusion-forming wire segment is adapted to press toward the opposing segment, thereby closing or occluding the aperture. Apertures or openings in other walls or membranes within the body or abnormally patent blood vessels may be similarly occluded.

Two embodiments of the inventive occlusion are described at column 2, lines 3-12, as follows:

> In one embodiment [Figures 8 and 9], the occlusion-forming wire segments may comprise essentially flat helices [62a, 62b], urged toward one another. In another embodiment [Figures 1-5], the wire may further include two foldable membranes [21a, 21b], one associated with each occlusion-forming wire segment. The membranes are folded for transport through the catheter along with the wire. Upon conversion of the wire to its preprogrammed configuration, the membranes unfold onto a frame produced by the occlusion-forming wire segments, one on each side of the aperture.

The Applied Prior Art

The references cited by the examiner against the appealed claims in the examiner's answer are:[1]

Dotter	4,503,569	Mar. 12, 1985
Wiktor	4,649,922	Mar. 17, 1987
Palmaz	4,776,337	Oct. 11, 1988
Munster et al (Munster)[2] (Germany)	DD-233,303	Feb. 26, 1986

The Rejections

Claims 1-5, 9, 11, 14, 15, 19, 21, 34-39, 41-44, 46-64, 66-68, 70-75, 77, 78 and 80 stand rejected under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, obvious under 35 U.S.C. § 103(a) over Munster.

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[1]The Dotter, Wiktor and Palmaz references were cited against the claims for the first time in the examiner's answer. The examiner justifies this circumstance by stating that "the newly cited references are added merely as evidence of the prior well known statement by the examiner in accordance with M.P.E.P. 1208.01" (answer, page 3). Appellant has not petitioned the Director pursuant to 37 CFR § 1.181 with respect to the citation of these references, or the rejections based thereon. See page 5 of the reply brief.

[2]Our understanding of this German language document is derived in part from a translation thereof provided by appellant. A copy of that translation is attached to the decision.

Claims 6, 16, 17, 20, 40 and 45 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Munster in view of Dotter.

Claims 10 and 20 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Munster in view of Wiktor.

Claims 7 and 8 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Munster in view of Palmaz.

Claims 12 and 13 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Munster.

Attention is directed to appellant's main and reply briefs (Paper Nos. 31 and 33) and to the examiner's answer (Paper No. 32) for the respective positions of appellant and the examiner regarding the merits of these rejections.

The Munster Reference

Munster, the starting point for each of the examiner's rejections, is directed to a device for occluding an aperture within a body surface.[3] Figure 1 shows a first embodiment of an

[3]Although Munster's drawing figures show the device occluding a duct between the body's main artery (aorta) and the pulmonary artery, it is clear that Munster contemplates the device being used to occlude an aperture in a body surface. See page 5 of the translation, lines 2-4 ("The present invention relates to an occluding object for occlusion of the *ductus arteriosus persistens* as well as other arteriopulmonary and other congenital or acquired arteriovenous fistulae, or heart defects.").

occluding device where the device comprises a wire of shape memory material which forms, when not influenced by outer forces, a so-called double helix configuration comprising relatively wide end portions 2, 3 and a narrow waist or central bridge portion 5. Figure 2 shows a second embodiment where the occluding device comprises several wire elements which comprise a central bridge portion 5 and a number of anchor arms 8 at each end of the bridge portion, which arms spread laterally when the device is subject to no external influences. The occluding device may be provided with textile fibers or bristles (elements 9 of Figure 1). Also, the bridge portion of the device may be provided with either an inflatable balloon (not shown) or a compressible, swelling plastic foam member (element 10 of Figure 2) to assist in occluding the aperture. In each embodiment, the ends of the occluding device are adapted to be compressed so that the device can be fit into a small diameter catheter (element 4 of Figure 3) for delivery to the site of the aperture to be occluded. When the device is released from the end of the catheter at the site of the aperture, the ends automatically re-assume the shape they exhibited when not influenced by outer forces (i.e., the shapes shown in Figures 1 and 2).

The method of placing the occluding device is set forth on pages 8-9 of the translation. Pertinent to the issues of patentability raised in the present case are the steps designated (e) through (k), which are reproduced below, with emphasis added:

e) positioning of the catheter in the duct is such a manner that the front side lies in the aorta-side opening of the duct;
f) introduction of the guide spiral provided with the holding wire and the occluding object, or the likewise-equipped plastic catheter, into the catheter situated in the body, in such a manner that the occluding object is situated inside the catheter lumen in a stretched form . . .
g) retraction of the catheter, the guide spiral being held fast, in such a manner that upon the retraction of the catheter the front, longer anchor arms of the occluding object emerge from the catheter mouth and *come to rest against* the wall of the aorta, or in the case of the use of the double helix, the (for now) still-stretched aorta-side end, is pushed out of the catheter up to the central bridge, spreads itself out into its original form, and *likewise comes to rest against* the aorta wall, in both cases, the occluding object is still held fast at the pulmonary-side end by means of the holding wire;
h) precise positioning of the aorta-side anchor arms, or as the case may be, the aorta-side end of the double helix, and further retraction of the catheter, until the pulmonary-side anchor arm or, as the case may be, the pulmonary end of the double helix, emerges from the catheter and *comes to rest against* the tissue around the opening of the duct on the pulmonary side;
i) *post-adjustment* of the occluding object with the aid of the guide spiral and the holding wire affixed therein;
j) letting the plastic swell up or inflating the balloon with an X-ray contrast agent at the central

bridge of the occluding object, *which is still fastened to the holding wire;*

k) injection of a contrast agent through the catheter *for checking the sufficiency of the tightness of the closing off of the duct* . . . .

Appellant's Article Claims

Analysis of whether a claim is patentable over the prior art begins with a determination of the scope of the claim. In the present case, we consider appellant's article claims to be directed to an occluding device *per se*, as opposed to an occlusion device positioned in an aperture in a body. Based on appellant's overall disclosure (see, for example, column 1, lines 61-65), we consider the claimed "preprogrammed configuration" of the occluding device to be the predetermined configuration the device is meant to assume when the device is at the normal body temperature of the site of its intended use. Based on appellant's overall disclosure (see, for example, column 1, lines 5-7; column 6, lines 18-22), we consider the terminology "occlusion-forming wire segments . . . urged toward one another" of representative claim 1, as well as the similar "urged toward one another" terminology of remaining independent article claims 9, 47, 57, 61-64 and 67, to mean that the wire segments of the claimed device are formed such that, in use, they press toward one another to engage the adjacent septal

surfaces of the aperture to be occluded with sufficient force to occlude (i.e., block blood flow through) the aperture.

Representative article claim 1 is directed to a device adapted to occlude (i.e., block blood flow through) an aperture within a body surface. The device comprises a wire having two configurations, one such configuration being an elongated configuration for passage through a catheter and through the aperture, and the other configuration being a "preprogrammed configuration" which includes "occlusion-forming wire segments one on each side of said aperture urged toward one another." The claimed device further includes means for causing the wire to change from the elongated configuration to the preprogrammed configuration inside the body, said means being a temperature responsive material construction of the wire, by which the wire is activated at body temperature, to assume the preprogrammed configuration.

In rejecting the appellant's article claims as being anticipated by or, in the alternative, obvious in view of Munster, the examiner has advanced several alternative theories as to how the occluding device of Munster meets or renders obvious the limitations of the independent claims calling for the device to have a "preprogrammed configuration" wherein the occlusion-forming

wire segments are "urged toward one another." First, the examiner contends (answer, page 5) that the wire segments of Munster are urged toward one another since they move radially outward and longitudinally toward each other as they emerge from the catheter. While we appreciate that the ends of Munster's device expand radially outwardly and most likely move toward each other, at least to some degree, as the device is being deployed, we must agree with appellant's argument on page 14 of the main brief that this circumstance does not meet the "urged toward each other" limitation of appellant's article claims in that these claims call for the occlusion-forming wire segments to be urged toward one another *in* the preprogrammed configuration, *not during the transition* of the occluding device from its elongated configuration into its preprogrammed configuration. Hence, the examiner's first theory of anticipation is not well taken.

Second, the examiner contends that Munster's disclosure that the ends of the occluding device come to rest against the tissue on the aorta and pulmonary arteries is sufficient to meet the "urged toward each other" language of the independent article claims because "it would certainly be very difficult, if not impossible, to size the Munster occluding member so that the wire segments, when they come to rest against the tissue, would not press against

the tissue even in infinitesimal amount (i.e., with exactly zero force). Note that the amount "urged" is not claimed" (answer, page 10). Our difficulty with this argument is that, based on our interpretation *supra* of the "urged toward each other" language in appellant's claims, we do not consider that merely coming to rest against the walls of aorta and pulmonary arteries as called for in Munster, or lightly touching such tissue, would necessarily result in a device capable of occluding (i.e., blocking of blood flow through) the duct, as we consider the claims to require. This is especially so in that, from our perspective, steps (g) through (k) of Munster indicate that the mere coming to rest of the ends of the device against the aorta and pulmonary arteries is *not*, in and of itself, sufficient to close off the duct therebetween. More particularly, Munster's step (i) of post adjustment of the occluding object with the aid of the guide spiral and the holding wire indicates to us that the occluding device is at this stage of deployment still rather loosely positioned relative to the duct, and Munster's step (j) of swelling the plastic member or inflating the balloon and step (k) of only thereafter checking the sufficiency of the tightness of the closing off of the duct indicate to us that the plastic member or balloon plays an

important role in attaining sufficient tightness to close off or occlude the duct.

Third, the examiner takes the alternative position in the paragraph spanning pages 5-6 of the answer that

> assuming *arguendo* that the Munster wire segments of occluding device 1 are not "occlusion-forming" because they do not press against the tissue with sufficient force to form an occlusion, these wire segments, with no modification, when placed on opposite sides of an anatomical member having a slightly longer aperture, would form an occlusion since they would press against the tissue with greater force since they would be farther away from their at rest, relaxed position.

In the present case, the examiner's assertion that Munster's teachings are sufficient to establish under the principles of inherency the particular "preprogrammed configuration" wherein the occlusion-forming wire segments are "urged toward one another" as called for in claim 1 and appellant's other independent article claims is totally without support in the Munster reference and entirely speculative on the examiner's part. In this regard, it is well settled that inherency may not be established by probabilities or possibilities, but must instead be "the natural result flowing from the operation as taught." *See In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981). Here, there is no basis to believe that the ends of Munster's Figure 1 embodiment *necessarily* would be urged toward one another in the event that embodiment was

placed in a duct of judiciously selected length slightly greater than that envisioned by the reference because, for all Munster teaches, the coils in the transition area between the ends of the device and the waist portion might simply contract to allow the length of the waist portion to "grow" to accommodate the increased length of the duct. As for Munster's Figure 2 embodiment, placing that device in a duct of slightly greater length than that envisioned by the reference also would not *necessarily* result in the kind of "urging toward each other" we consider the claims to require[4] since in this circumstance the occlusion function (i.e., blockage of blood flow) might be derived only from the swellable plastic member 10 or inflatable balloon this embodiment would appear to require. In light of the above, neither the Munster reference nor the examiner's reasoning provides an adequate factual basis to establish that the natural result flowing from following

---

[4]As stated *supra*, we consider the terminology "occlusion-forming wire segments . . . urged toward one another" of representative claim 1, as well as the similar "urged toward one another" terminology of remaining independent article claims 9, 47, 57, 61-64 and 67, to mean that the wire segments of the claimed device are formed such that, in use, they press toward one another to engage the adjacent septal surfaces of the aperture to be occluded *with sufficient force to occlude (i.e., block blood flow through)* the aperture.

the teachings of Munster would be an occluding device like that claimed by appellant in the appealed article claims.

Looking finally at the examiner's 35 U.S.C. § 103(a) rejection of claim 1 et al. as being unpatentable over Munster, the examiner posits on page 10 of the answer that "[t]here is no teaching in Munster that the wire segments, as they are intended to operate, do not press against the tissue," and that "[i]t certainly would have been obvious to size them so that they press against tissue when implanted in the body in order to insure that they come to rest against tissue as intended."

Rejections based on 35 U.S.C. § 103 must rest on a factual basis. In making such a rejection, the examiner has the initial duty of supplying the requisite factual basis and may not, because of doubts that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in the factual basis. *In re Warner*, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967), *cert. denied*, 389 U.S. 1057 (1968). Moreover, while common knowledge and common sense may be applied to the analysis of evidence relied upon in making a rejection under 35 U.S.C. § 103, they are not a substitute for evidence. *In re Lee*, 277 F.3d 1338, 1345, 61 USPQ2d 1430, 1435 (Fed. Cir. 2002). Here, the examiner's attempt to bridge the

evidentiary gap between Munster and the claimed invention under the cover of what "certainly would have been obvious" to one of ordinary skill in the art and/or the circumstance that there is no teaching in Munster of the wire segments not pressing against the tissue is unavailing in that it rests on undue speculation and unfounded assumptions as to how the artisan might have gone about applying the teachings of Munster to repair congenital or acquired heart defects or the like. In this regard, the mere fact that the prior art could be modified to arrive at the claimed subject matter does not suffice. *See In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984)).

In light of the foregoing, we shall not sustain the examiner's rejection of claims 1-5, 9, 15, 19, 21, 34-39, 41-44, 46-64, 66-68, 70-75, 77, 78 and 80 as being anticipated by or, in the alternative, obvious over Munster.

Claims 6, 16, 17, 20, 40 and 45 stand rejected as being unpatentable further in view of Dotter, claims 10 and 20 stand rejected as being unpatentable further in view of Wiktor, and claims 7 and 8 stand rejected further in view of Palmaz. We have carefully reviewed the teachings of Dotter, Wiktor and Palmaz but find nothing therein which makes up for the deficiencies of Munster

discussed above. Accordingly, we also shall not sustain the standing § 103 rejections of these dependent claims.

Appellant's Method Claims

Independent method claim 11 is directed to a method of occluding an aperture with a body surface. Claim 11 positively calls for, among other things, the steps of deploying a wire of temperature responsive material in an elongated configuration through a catheter, permitting the wire to assume a preprogrammed configuration whereupon an occlusion-forming wire segment on the distal side of the aperture is urged toward the aperture, and withdrawing the catheter thereby deploying an additional length of wire on the proximal side of the aperture whereupon the additional length of wire is permitted to assume a preprogrammed configuration including an opposing occlusion-forming wire segment urged toward the aperture on the proximal side of the aperture.

The views we expressed above concerning the rejection of appellant's article claims apply with equal force to the examiner's rejection of method claims 11, and claims 12-14 that depend therefrom. Simply stated, Munster does not anticipate or render obvious appellant's method claims any more than it did appellant's article claims. Accordingly, we also shall not sustain the

standing rejection of claims 11-14 as being anticipated by or obvious in view of Munster.

Conclusion

Each of the standing rejections is reversed.

The decision of the examiner finally rejecting the appealed claims is reversed.

REVERSED

IRWIN CHARLES COHEN
Administrative Patent Judge

LAWRENCE J. STAAB
Administrative Patent Judge

JEFFREY V. NASE
Administrative Patent Judge

BOARD OF PATENT
APPEALS
AND
INTERFERENCES

LJS/lp

Appeal No. 2004-1453
Reexamination Control No. 90/006,043

BLANK ROME LLP
600 NEW HAMPSHIRE AVENUE, NW
WASHINGTON, DC 20037

EXHIBIT K

Press Release

Source: NMT Medical, Inc.

NMT Medical Announces Favorable Decision by U.S. Patent Office Board of Appeals

Tuesday September 7, 3:16 pm ET

BOSTON, Sept. 7 /PRNewswire-FirstCall/ -- NMT Medical, Inc. (Nasdaq: NMTI - News) today announced a favorable decision by the U.S. Patent and Trademark Office Board of Appeals relating to the Company's patent infringement actions against AGA Medical Corp.

In December 1998, NMT filed a patent infringement suit against AGA Medical claiming that certain of AGA's products infringe U.S. Patent No. 5,108,420 (the '420 Patent), which is exclusively licensed by NMT. During the litigation, AGA identified certain third party patents that it argued would invalidate the claims of the '420 Patent. In September 2003, the Court dismissed NMT's suit against AGA without prejudice to NMT's ability to refile the suit after the conclusion of the reexamination proceedings.

Although a Patent Office examiner initially rejected the claims of the '420 Patent, the Patent Office Board of Appeals reversed the examiner's rejection of the claims on August 19, 2004 and returned the reexamination for action consistent with its decision.

John E. Ahern, NMT's President and CEO, said, "The Board of Appeals' decision represents an important step in our patent infringement efforts against AGA. As a medical technology innovator, NMT Medical has developed and obtained the rights to an impressive portfolio of patents and intellectual property that we will continue to defend aggressively."

About NMT Medical, Inc.

NMT Medical designs, develops and markets proprietary implant technologies that allow interventional cardiologists to treat cardiac sources of stroke and other brain attacks through minimally invasive, catheter-based procedures. NMT Medical is investigating the potential connection between a common cardiac defect called a patent foramen ovale (PFO) and brain attacks such as stroke, transient ischemic attacks (TIA's) and migraine headaches. A PFO can allow venous blood, unfiltered by the lungs, to enter the arterial circulation of the brain possibly triggering a cerebral event or brain attack. NMT is the leader in designing and developing implants to seal the PFO defect in a minimally invasive, catheter-based procedure performed by the interventional cardiologist.

Stroke is the third leading cause of death in the United States and leading cause of disability in adults. Each year 750,000 Americans suffer a new or recurrent stroke and 500,000 Americans experience a TIA. The prevalence of migraines in the United States is about 10%. Of the 28 million migraine sufferers in America, three out of four are women. Migraines have increased 50% in the last 20 years.

The Company also serves the pediatric interventional cardiologist with a broad range of cardiac

septal repair implants delivered with nonsurgical catheter techniques. For more information about NMT Medical, please visit http://www.nmtmedical.com.

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements -- including statements regarding the timing and ultimate outcome of any administrative and litigation proceedings to enforce the Company's intellectual property rights and the Company's financial, sales and profitability expectations, expansion of the Company's cardiovascular business and market opportunities, including migraines and any other new applications for our technology or products, the timing, cost and outcome of CLOSURE I, expected patient enrollment levels and the timing thereof, regulatory approvals for the Company's products, new products and product developments -- involve known and unknown risks, uncertainties or other factors which may cause actual results, performance or achievements of the Company to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Factors that may cause such a difference include, but are not limited to, the risk factors discussed under the heading "Certain Factors That May Affect Future Results" included in Management's Discussion and Analysis of Financial Condition and Results of Operations in the Company's Annual Report on Form 10- K for the year ended December 31, 2003, as amended, and subsequent filings with the U.S. Securities and Exchange Commission.

Contact:
John E. Ahern
President & Chief Executive officer
NMT Medical, Inc.
(617) 737-0930
jea@nmtmedical.com

Source: NMT Medical, Inc.

EXHIBIT L

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/006,043	06/25/2001	5108420	000365.00002	4983

27557 7590 01/26/2005

BLANK ROME LLP
600 NEW HAMPSHIRE AVENUE, N.W.
WASHINGTON, DC 20037

EXAMINER	
THALER, M.	
ART UNIT	**PAPER NUMBER**
3731	41

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Notice of Intent to Issue Ex Parte Reexamination Certificate	Control No.	Patent Under Reexamination	
	90/006,043	5108420	
	Examiner	Art Unit	
	Michael Thaler	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

1. ☒ Prosecution on the merits is (or remains) closed in this ex parte reexamination proceeding. This proceeding is subject to reopening at the initiative of the Office or upon petition. Cf. 37 CFR 1.313(a). A Certificate will be issued in view of

(a) ☐ Patent owner's communication(s) filed: _____.

(b) ☐ Patent owner's late response filed: _____.

(c) ☐ Patent owner's failure to file an appropriate response to the Office action mailed: _____.

(d) ☐ Patent owner's failure to timely file an Appeal Brief (37 CFR 1.192).

(e) ☒ Other: *Decision by Board of Patent Appeals and Interferences*.

Status of *Ex Parte* Reexamination:

(f) Change in the Specification: ☒ Yes, ☐ No

(g) Change in the Drawing: ☒ Yes, ☐ No

(h) Status of the Claim(s):

(1) Patent claim(s) confirmed: 1-14.

(2) Patent claim(s) amended (including dependent on amended claim(s)): _____.

(3) Patent claim(s) cancelled: _____.

(4) Newly presented claim(s) patentable: 15-17,19-21 and 34-80.

(5) Newly presented cancelled claims: 18 and 22-33.

2. ☒ Note the attached statement of reasons for patentability and/or confirmation. Any comments considered necessary by patent owner regarding reasons for patentability and/or confirmation must be submitted promptly to avoid processing delays. Such submission(s) should be labeled: "Comments On Statement of Reasons for Patentability and/or Confirmation."

3. ☐ Note attached NOTICE OF REFERENCES CITED (PTO-892).

4. ☒ Note attached LIST OF REFERENCES CITED (PTO-1449).

5. ☒ The drawing ~~correction request~~ filed on 11/24/04 is: ☒ approved ☐ disapproved.

6. ☐ Acknowledgment is made of the priority claim under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some* c)☐ None of the certified copies have

☐ been received.

☐ not been received.

☐ been filed in Application No. _____.

☐ been filed in reexamination Control No. _____.

☐ been received by the International Bureau in PCT Application No. _____.

* Certified copies not received: _____.

7. ☐ Note attached Examiner's Amendment.

8. ☐ Note attached Interview Summary (PTO-474)

9. ☐ Other: _____

Michael Thaler
Primary Examiner
Art Unit: 3731

cc: Requester (if third party requester)

STATEMENT OF REASONS FOR PATENTABILITY AND/OR CONFIRMATION

The following is an examiner's statement of reasons for patentability and/or confirmation of the claims found patentable in this reexamination proceeding: The reason for the patentability and confirmation of the claims is the Decision by the Board of Patent Appeals and Interferences rendered August 19, 2004.

Any comments considered necessary by PATENT OWNER regarding the above statement must be submitted promptly to avoid processing delays. Such submission by the patent owner should be labeled: "Comments on Statement of Reasons for Patentability and/or Confirmation" and will be placed in the reexamination file.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (571)272-4704. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

mht
1/11/05

MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731

PATENT AND TRADEMARK OFFICE

LIST OF REFERENCES CITED BY PATENTEE

PATENTEE	Lloyd A. MARKS
FILING DATE	April 28, 1992
GROUP	3731

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
JT	4,665,906	05/19/1987	Jervis	606	78	

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION YES	TRANSLATION NO

OTHER REFERENCES

JT	"Transcatheter Closure of Atrial Septal Defects," Lock et al., Circulation, Vol. 79, No. 5, May 1989
JT	Letter from Defendant AGA's Attorney dated October 14, 2004 (3-pages)

Examiner [signature] Date Considered 1-11-05

*Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to patentee.

EXHIBIT M

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

NMT MEDICAL, INC.,

Plaintiff,

v.

AGA MEDICAL CORPORATION,

Defendant.

Civil Action No. 04 12565 NG

JURY TRIAL DEMANDED

COMPLAINT FOR PATENT INFRINGEMENT

NATURE OF ACTION

This is an action under the patent laws of the United States, Title 35 of the United States Code, for infringement of United States Patent No. 5,108,420.

THE PARTIES

1. Plaintiff NMT Medical, Inc. ("NMT") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business in Boston, Massachusetts.

2. Defendant AGA Medical Corporation ("AGA"), is a Minnesota corporation, having its principal place of business in Golden Valley, Minnesota.

JURISDICTION AND VENUE

3. This is an action for patent infringement arising under Title 35 of the United States Code. Accordingly, this Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1338(a).

4. Venue is proper in this jurisdiction pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and/or 1400(b).

ACTS GIVING RISE TO THE COMPLAINT

5. Plaintiff NMT is the exclusive worldwide licensee of the right to make, use, and sell products embodying and/or manufactured according to the methods of United States Patent No. 5,108,420 (the "420 patent"), entitled "Aperture Occlusion Device." A complete and true copy of the '420 patent is attached as Exhibit A.

6. On December 10, 1998, NMT commenced litigation against AGA in this Court, alleging infringement of the '420 Patent. That litigation was captioned Nitinol Medical Technologies, Inc. v. AGA Medical Corp., 98-cv-12506-NG.

7. During the course of the parties' prior litigation, it became clear that two pieces of purported prior art were not before the Patent and Trademark Office ("PTO") when the '420 patent originally was prosecuted.

8. On April 25, 2001, the Court granted NMT's motion to stay the proceedings in the parties' original litigation pending reexamination of the '420 patent by the PTO.

9. Thereafter, on June 25, 2001, the inventor of the '420 patent voluntarily submitted the '420 patent to the PRO for reexamination in light of the purported prior art.

10. The Court held periodic status conferences during the following sixteen months. After each conference, the Court continued its order staying the proceedings. At a status conference on October 31, 2002, the Court indicated that it would consider dismissing the parties' original litigation without prejudice if the PTO did not issue a decision on the reexamination proceeding by the end of 2002.

11. On February 5, 2003, the PTO examiner conducting the reexamination rejected all of the claims of the '420 patent. NMT timely sought review of the PTO examiner's determination before the Board of Patent Appeals and Interferences.

12. On September 30, 2003, by letter to the Court, AGA requested that the ongoing stay of the parties' original litigation be converted into a dismissal without prejudice.

13. On December 2, 2003, while the PTO appeal was pending, the Court dismissed the parties' original litigation, without prejudice to NMT's right to refile the case in this Court depending upon the outcome of the PTO reexamination proceedings.

14. On August 19, 2004, the Board of Patent Appeals and Interferences reversed the PTO examiner's initial determination and found that the two pieces of purported prior art did not invalidate the claims of the '420 patent. The PTO Board remanded the '420 patent to the PTO examiner for proceedings consistent with the Board's decision.

15. On October 13, 2004, AGA brought a complaint against NMT in the District of Minnesota for a declaratory judgment regarding the issues of infringement and validity with respect to the '420 patent. AGA's Minnesota Complaint raises the same claims and defenses with regard to the '420 patent that were before this Court in the parties' original litigation.

COUNT I: INFRINGEMENT

16. NMT restates Paragraphs 1 – 15 of this Complaint.

17. AGA manufactures, offers for sale, or sells medical devices which infringe one or more of the claims of the '420 patent.

18. On information and belief, AGA's acts of infringement are willful and deliberate.

PRAYER FOR RELIEF

WHEREFORE, NMT requests that judgment be entered in its favor and that it be granted the following relief:

1. A judgment that AGA has infringed the '420 patent, and that such infringement has been willful;

2. A permanent injunction restraining AGA, its officers, agents, servants, and employees, and those acting in concert with it, from infringing the '420 patent.

3. An award of damages sufficient to compensate NMT for the infringement complained of herein;

4. An award of enhanced damages in the amount of three times the damages found or assessed, attorneys' fees, disbursements, and costs of suit; and

5. Such other and further relief as the Court deems just and proper.

JURY TRIAL DEMAND

PLAINTIFFS HEREBY DEMAND TRIAL BY JURY.

Dated: December 7, 2004.

NMT MEDICAL, INC.

By its attorneys,

Dominic E. Massa (BBO #564694)
Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, Massachusetts 02109
(617) 526-6000

EXHIBIT N

UNITED STATES DISTRICT COURT

District of Massachusetts

NMT Medical, Inc.

V.

AGA Medical Corp.

SUMMONS IN A CIVIL ACTION

CASE NUMBER:

04 12565 NG

TO: (Name and address of Defendant)

AGA Medical Corp.
682 Mendelssohn Ave.
Golden Valley, MN 55427

YOU ARE HEREBY SUMMONED and required to serve on PLAINTIFF'S ATTORNEY (name and address)

Dominic E. Massa, Esq.
Wilmer Cutler Pickering Hale and Dorr
60 State Street
Boston, MA 02109

answer to the complaint which is served on you with this summons, within 20 (twenty) days after service this summons on you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you : the relief demanded in the complaint. Any answer that you serve on the parties to this action must be filed with the erk of this Court within a reasonable period of time after service.

TONY ANASTAS

ERK

DATE 12/7/2004

DEPUTY CLERK

RETURN OF SERVICE

UNITED STATES DISTRICT COURT
District of Minnesota

Case Number: 04-4486JMR/FLN

Plaintiff:
AGA Medical Corporation

vs.

Defendant:
Nitinol Medical Technologies, Inc., et al

Received by MASS CONSTABLE SERVICE to be served on **NITINOL MEDICAL TECHNOLOGIES, 27 Wormwood St., Boston, MA 02210.**

I, David Brown, do hereby affirm that on the **20th day of January, 2005 at 1:40 pm, I:**

Served a true and attested copy of the **US Summons; Complaint; Civil Cover Sheet; Exhibit to Nitinol Medical Technologies** in the following manner, by delivering in hand to **Jessina Hue, authorized agent.** . Said service was made at **27 Wormwood St., Boston, MA 02210 .**

Description of Person Served: Age: 30, Sex: F, Race/Skin Color: Black, Height: 5'6", Weight: 130, Hair: Black, Glasses: N

I certify that I am over the age of 18, have no interest in the above action.

David Brown
Process Server

MASS CONSTABLE SERVICE
1004 Pheasant Lane
Middleboro, MA 02346
(800) 249-3155

Our Job Serial Number: 2005000185
Ref: 543

AO 440 (Rev. 10/93) Summons in a Civil Action – SDNY WEB 4/99

RETURN OF SERVICE

Service of the Summons and Complaint was made by me[1]	DATE 1/20/05
NAME OF SERVER ALFONSE R. CARLUCCI	TITLE Process Server

Check one box below to indicate appropriate method of service

☐ Served personally upon the defendant. Place where served: _____

☒ Left copies thereof at the defendant's dwelling house or usual place of abode with a person of suitable age and discretion then residing therein.
Name of person with whom the summons and complaint were left: JANICE SIEGEL, WIFE

☐ Returned unexecuted: _____

☐ Other *(specify)*: _____

STATEMENT OF SERVICE FEES

TRAVEL	SERVICES	TOTAL

DECLARATION OF SERVER

I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Return of Service and Statement of Service Fees is true and correct.

Executed on 1.20.05
Date

Signature of Server

7 Woodside Rd, Springfield, NJ 07081
Address of Server

(1) As to who may serve a summons see Rule 4 of the Federal Rules of Civil Procedure.

2298

EXHIBIT O

AO 440 (Rev. 10/93) Summons in a Civil Action

UNITED STATES DISTRICT COURT

District of

AGA MEDICAL CORPORATION

V.

Nitinol Medical Technologies, Inc.,
d/b/a/ NMT Medical, Inc, and
Lloyd A. Marks

SUMMONS IN A CIVIL CASE

CASE NUMBER: 04-4486JMR/FLN

TO: (Name and address of Defendant)

NITINOL MEDICAL TECHNOLOGIES
27 WORMWOOD ST
BOSTON, MA 02210-1619 UNITED STATES

Mr. Lloyd A. Marks
1021 MINISINK WAY
WESTFIELD, NJ 07090-3722

YOU ARE HEREBY SUMMONED and required to serve upon PLAINTIFF'S ATTORNEY (name and address)

James T. Nikolai (#0144101)
NIKOLAI & MERSEREAU, P.A.
900 Second Avenue South
820 International Center
Minneapolis, MN 55402

an answer to the complaint which is herewith served upon you, within 20 days after service of this summons upon you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. You must also file your answer with the Clerk of this Court within a reasonable period of time after service.

RICHARD D. SLETTEN
CLERK

OCT 13 2004
DATE

D. LaFond
(By) DEPUTY CLERK

ORIGINAL

STATE OF MINNESOTA

COUNTY OF HENNEPIN

AFFIDAVIT OF SERVICE

METRO LEGAL SERVICES

Thomas V. Strandberg, being duly sworn, on oath says: that on the 20th day of January, 2005, at 3:40 p.m. (s)he served the attached Summons; Civil Cover Sheet; and Complaint upon AGA Medical Corp therein named, personally at 682 Mendelssohn Avenue, Golden Valley, County of Hennepin, State of Minnesota, by handing to and leaving with David Aberle, Chief Financial Officer, a true and correct copy thereof.

Subscribed and sworn to before me,
January 21, 2005.

Rose Batsell
Notary Public

ROSE BATSELL
NOTARY PUBLIC-MINNESOTA
My Commission Expires Jan. 31, 2010

Thomas V Strandberg

Re: NMT Medical

AO 440 (Rev. 8/01) Summons in a Civil Action

RETURN OF SERVICE

Service of the Summons and complaint was made by me[1]	DATE
NAME OF SERVER *(PRINT)*	TITLE

Check one box below to indicate appropriate method of service

☐ Served personally upon the defendant. Place where served:

☐ Left copies thereof at the defendant's dwelling house or usual place of abode with a person of suitable age and discretion then residing therein.

Name of person with whom the summons and complaint were left:

☐ Returned unexecuted:

☐ Other (specify):

STATEMENT OF SERVICE FEES

TRAVEL	SERVICES	TOTAL
		$0.00

DECLARATION OF SERVER

I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Return of Service and Statement of Service Fees is true and correct.

Executed on _____ _____
Date *Signature of Server*

_____
Address of Server

1) As to who may serve a summons see Rule 4 of the Federal Rules of Civil Procedure.

EXHIBIT P

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

NITINOL MEDICAL TECHNOLOGIES, Inc. and LLYOD A. MARKS, Plaintiffs, v. AGA MEDICAL CORPORATION, Defendant.	Civil Action No. 98-12506-NG

PLAINTIFFS' INITIAL DISCLOSURES
PURSUANT TO LOCAL RULE 26.2 and FED. R. CIV. P. 26(a)(1)

Pursuant to Local Rule 26.2 and Fed. R. Civ. P. 26(a)(1), plaintiffs Nitinol Medical Technologies, Inc. and Lloyd A. Marks (collectively, "NMT") make the following initial disclosures to defendant AGA Medical Corporation ("AGA").

A. Individuals Likely to Have Relevant Discoverable Information

Individual	Subject of Information
Lloyd A. Marks 1021 Minisink Way Westfield, NJ 07090 (908) 789-0512	Information related to the allegations in the Complaint, including information regarding the invention of the '420 patent, prosecution of the '420 patent, prior art to the '420 patent, and licensing of the '420 patent.

Thomas M. Tully 27 Wormwood Street Boston, MA 02210 (617) 737-0930	Information related to the allegations in the Complaint and AGA's Counterclaims, including information regarding licensing of the '420 patent, AGA's infringement of the '420 patent, NMT's dealings with AGA, NMT's sales and marketing of occlusion devices, and NMT's damages resulting from AGA's activities.
Stephen J. Kleshinski 27 Wormwood Street Boston, MA 02210 (617) 737-0930	Information related to the allegations in the Complaint and AGA's Counterclaims, including information regarding AGA's infringement of the '420 patent, NMT's sales and marketing of occlusion devices, and NMT's damages resulting from AGA's activities.
Carol Ryan 27 Wormwood Street Boston, MA 02210 (617) 737-0930	Information related to the allegations in the Complaint and AGA's Counterclaims, including information regarding NMT's and AGA's occlusion devices.
John Wright 27 Wormwood Street Boston, MA 02210 (617) 737-0930	Information related to the allegations in the Complaint and AGA's Counterclaims, including information regarding NMT's and AGA's occlusion devices.
Denise Goodine 27 Wormwood Street Boston, MA 02210 (617) 737-0930	Information related to the allegations in the Complaint and AGA's Counterclaims, including information regarding NMT's and AGA's occlusion devices.
Rudy Davis 27 Wormwood Street Boston, MA 02210 (617) 737-0930	Information related to the allegations in the Complaint and AGA's Counterclaims, including information regarding sales and marketing of NMT's occlusion devices and NMT's damages resulting from AGA's activities.

William J. Knight 27 Wormwood Street Boston, MA 02210 (617) 737-0930	Information related to the allegations in the Complaint, including information regarding NMT's damages resulting from AGA's activities.
Daniel W. Sixbey, Esq. Sixbey, Friedman, Leedom & Ferguson 2010 Corporate Ridge, Suite 600 McLean, VA 22102	Subject to the attorney-client privilege and work product doctrine, information related to the allegations in the Complaint, including information regarding the prosecution of the '420 patent, prior art to the '420 patent, and licensing of the '420 patent.
Paul F. Prestia, Esq. Ratner & Prestia P.O. Box 980 Valley Forge, PA 19482	Subject to the attorney-client privilege and work product doctrine, information related to the allegations in the Complaint, including information regarding the prosecution of the '420 patent, prior art to the '420 patent, and licensing of the '420 patent.
Kurt Amplatz 682 Mendelssohn Ave. Golden Valley, MN 55427	NMT believes Mr. Amplatz has information related to the allegations in the Complaint, including information regarding AGA's infringement of the '420 patent and NMT's dealings with AGA.
Franck Gougeon 682 Mendelssohn Ave. Golden Valley, MN 55427	NMT believes Mr. Gougeon has information related to the allegations in the Complaint, including information regarding AGA's infringement of the '420 patent and NMT's dealings with AGA.
Frank Kotula	NMT believes Mr. Kotula has information related to the allegations in the Complaint, including information regarding AGA's infringement of the '420 patent.
Curtis Amplatz	NMT believes Mr. Amplatz has information related to the allegations in the Complaint, including information regarding AGA's infringement of the '420 patent.

NMT reserves the right to supplement the foregoing list of individuals as discovery progresses in this action.

B. Description of Relevant Documents

United States Patent No. 5,108,420 and its file history.

Agreement between NMT and Lloyd A. Marks regarding United States Patent No. 5,108,420.

References cited in the '420 patent.

Advertising, marketing, and financial documents concerning NMT's occlusion devices.

United States Patent No. 5,725,552 and its file history.

United States Patent No. 5,846,261.

Correspondence between representatives of AGA and NMT.

Copies of pages printed from AGA's web site.

Publications related to occlusion devices.

Relevant documents within the above categories are in the possession of NMT or its counsel, Hale and Dorr LLP, and, except for those documents protected from discovery by the attorney-client privilege or work product doctrine, will be made available for inspection at the offices Hale and Dorr LLP, 60 State Street, Boston, Massachusetts 02109, at a mutually agreeable time, subject to the entry of an acceptable Protective Order.

C. Computation of Damages

NMT charges that AGA has infringed and continues to infringe U.S. Patent No. 5,108,420. NMT charges that such infringement has been wilful. The computation of NMT's damages requires information that is only in the possession, custody, or control of AGA. This information includes, among other things, the number of infringing products AGA has made, used, and sold; the number of ancillary products AGA has made, used, and sold; the selling price of these products; and the profits generated as a result of these sales.

In addition to injunctive relief, NMT seeks damages adequate to compensate NMT for AGA's infringement. NMT's damages include profits that NMT has lost as a result of AGA's infringement. In no event are NMT's damages less than a reasonable royalty on AGA's making, using, and selling the patented invention.

NMT also requests that the court treble the amount of damages found or assessed in view of AGA's willful infringement, and claims attorney fees pursuant to 35 U.S.C. § 284. NMT also seeks prejudgment interest from the date of infringement to the date of judgment and costs to be fixed by the court. It is premature to calculate the amount of these damages at this time.

NMT will make available for inspection and copying the documents or other evidentiary material, not privileged or protected from disclosure, on which NMT's ultimate damages computation will be based.

D. Insurance

NMT carries general liability insurance issued by St. Paul Fire and Marine Insurance Co., which may be available to satisfy part or all of any judgment against NMT on AGA's Counterclaims. NMT will make its insurance policies available for inspection and copying.

NITINOL MEDICAL TECHNOLOGIES, INC. and LLOYD A. MARKS

By their attorneys,

Dated: June 24, 1999

William F. Lee (BBO #291960)
Dominic E. Massa (BBO #564694)
HALE AND DORR LLP
60 State Street
Boston, Massachusetts 02109
(617) 526-6000

William G. McElwain (BBO #332510)
HALE AND DORR LLP
1455 Pennsylvania Ave., N.W.
Washington, D.C. 20004
(202) 942-8400

EXHIBIT Q

6/18/99 (5)

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

NITINOL MEDICAL TECHNOLOGIES, INC. and LLYOD A. MARKS,

Plaintiffs,

v.

AGA MEDICAL CORPORATION,

Defendant.

Civ. No. 98 CV 12506NG

DEFENDANT / COUNTERCLAIM PLAINTIFF'S INITIAL DISCLOSURE PURSUANT TO LOCAL RULE 26.2 AND FED. R. CIV. P. 26(a)(1)

Pursuant to Local Rule 26.2 and Fed. R. Civ. P. 26(a)(1), Defendant / Counterclaim Plaintiff AGA Medical Corporation (hereinafter referred to as "AGA Medical") makes the following preliminary and voluntary disclosures to Plaintiff / Counterclaim Defendants Nitinol Medical Technologies, Inc. and Llyod A. Marks (hereinafter collectively referred to as "Nitinol") regarding the above-captioned action.

INITIAL DISCLOSURES

A. The following is a list of names, known addresses and telephone numbers for each individual that Defendant / Counterclaim Plaintiff is aware of, who may likely have discoverable

information relevant to disputed facts alleged with particularity in the pleadings and an identification of the subjects of information for each identified individual.

PERSON/KNOWN ADDRESS/PHONE	SUBJECT OF INFORMATION
Dr. Kurt Amplatz 682 Mendelssohn Ave. Golden Valley, MN 55427 612-513-9227	Information related to the facts alleged in AGA Medical's counterclaims; information related AGA Medical's septal occluding products; information related to septal occluding products produced currently or in the past by companies other than AGA Medical; and, information related to Nitinol's false advertising and deceptive trade practices
Franck Gougeon 682 Mendelssohn Ave. Golden Valley, MN 55427 612-513-9227	Information related to the facts alleged in AGA Medical's counterclaims; information related AGA Medical's septal occluding products; information related to septal occluding products produced currently or in the past by companies other than AGA Medical; and, information related to Nitinol's false advertising and deceptive trade practices
Michael R. Afremov 682 Mendelssohn Ave. Golden Valley, MN 55427 612-513-9227	Information related to AGA Medical's septal occluding products
Lloyd A. Marks	Without any limitation intended, Defendant / Counterclaim Plaintiff believes that Lloyd A. Marks has information related to the facts alleged in the Nitinol complaint and the facts alleged in AGA Medical's counterclaims, including, without limitation information related to septal occluding products produced currently or in the past by companies other than AGA Medical; and, technical information contradictory to Nitinol's advertising;
Thomas M. Tully 27 Wormwood Street Boston, MA 02210-1625	Without any limitation intended, Defendant / Counterclaim Plaintiff believes that Thomas M. Tully has information relevant to: facts alleged

	in the Nitinol complaint and facts alleged in AGA Medical's counterclaims; information related to case studies utilizing septal occluding devices; information related to experiments of septal occluding devces; information related to advancements over the years in the septal occluding technology; information related to septal occluding products produced currently or in the past by companies other than AGA Medical; information related to Nitinol's capacity to manufacture septal occluding products and the market for such products; information related to past and current production and sales by Nitinol of devices manufactured in accordance with the teachings of U.S. Patent No. 5,108,420; information related to communications concerning septal occluding devices
Past and/or current agents of Nitinol Medical Technologies, Inc.	Without any limitation intended, Defendant / Counterclaim Plaintiff believes that certain yet-to-be identified past or current agent(s) of Nitinol Medical Technologies have information relevant to: facts alleged in the Nitinol complaint and facts alleged in AGA Medical's counterclaims; information related to case studies utilizing septal occluding devices; information related to experiments of septal occluding devces; information related to advancements over the years in the septal occluding technology; information related to septal occluding products produced currently or in the past by companies other than AGA Medical; information related to Nitinol's capacity to manufacture septal occluding products and the market for such products; information related to past and current production and sales by Nitinol of devices manufactured in accordance with the teachings of U.S. Patent No. 5,108,420; information related to communications by agents of Nitinol Medical concerning septal occluding devices
Past and/or current agents of Temple University	Without any limitation intended, Defendant /

	Counterclaim Plaintiff believes that certain yet-to-be identified past or current agent(s) of Temple University have information relevant to U.S. Patent No. 5,108,420
Dr. K. Wright, PhD Houston, Texas	Information concerning a septal occluding device having helical coils urged towards one another, wherein said device was created prior to 1991
Dr. Terry D. King	Information concerning septal occluding devices created prior to 1991
Dr. Syamasundar Rao St. Louis, Missouri	Information concerning septal occluding devices created prior to 1991
Dr. Duncan Irving, MB, BS, FRCR 170 Coleherne Court Redcliffe Gardens London SW5 0DX	Information concerning known septal occluding devices shown or described prior to 1991

AGA Medical reserves the right to supplement the foregoing list of potential witnesses as discovery progresses in this action.

B. As currently advised, AGA Medical believes that the following documents and things in its possession, custody or control are relevant to the disputed facts alleged with particularity in the pleadings in this action:

a. Copy of U.S. Patent No. 5,108,420 and its file history;

b. Physical specimens of atrial septal defect occluding devices;

c. Documents relating to atrial septal defect occluding devices manufactured and/or sold by third parties;

d. Correspondence between representatives of AGA Medical and Nitinol, relating to atrial septal defect occluding devices and the '420 patent;

e. Copies of pages printed from Nitinol's web page;

f. Written publications, published prior to 1990 related to atrial septal defect occluding devices;

g. Copy of U.S. Patent No. 4,917,089;

h. Copy of U.S. Patent No. 4,655,771;

i. Affidavit of Michael R. Afremov; and

j. video showing the absence of any response by AGA Medical's septal occluding product to temperature changes.

A copy of the Affidavit of Michael R. Afremov has been numbered and included with this disclosure; the remaining documents and things are presently in the possession of AGA Medical or its counsel, Nikolai, Mersereau & Dietz, 900 Second Ave. South, 820 International Centre, Minneapolis, Minnesota 55402 and will be produced for inspection and copying at its counsel's office at a mutually convenient time.

C. AGA Medical seeks injunctive relief as well as damages for Nitinol's violations of 15 U.S.C. § 1125(a) and M.G.L.A. c.93A, § 11. The total extent of the harm and damage from past and continuing acts of Nitinol in violation of 15 U.S.C. § 1125(a) and M.G.L.A. c.93A, § 11 has yet to be completely realized, since information necessary to calculate the damages is in Nitinol's possession. Further, the computations of attorneys' fees and costs at this time is incomplete. AGA Medical reserves the right to provide the same after relevant discovery is taken.

D. As currently advised, Defendant / Counterclaim Plaintiff is not aware of an

insurance carrier which may be liable to indemnify, reimburse or satisfy all or any part of a judgment which may be entered in this action.

AGA MEDICAL CORPORATION

By Its Attorneys,

Dated: 6-8-99

Thomas C. O'Konski, Esq. (BBO # 378265)
Michael R. Reinemann, Esq. (BBO # 556,808)
Cesari and McKenna, L.L.P.
30 Rowes Wharf
Boston, Massachusetts 02110
(617) 951-2500

Of Counsel:

Paul T. Dietz, Esq.
Nikolai, Mersereau & Dietz, P.A.
900 Second Avenue South, Suite 820
Minneapolis, Minnesota 55402
(612) 339-7461

CERTIFICATE OF SERVICE

I hereby certify that a true copy of the foregoing was served upon the following counsel of record by Hand on June 8, 1999:

William G. McElwain, Esq.
Hale and Dorr, LLP
60 State Street
Boston, MA 02109

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

NITINOL MEDICAL TECHNOLOGIES, INC. and LLYOD A. MARKS,

Plaintiffs,

v.

AGA MEDICAL CORPORATION,

Defendant.

Civ. No. 98 CV 12506NG

AFFIDAVIT

AFFIDAVIT OF MICHAEL R. AFREMOV

STATE OF)
) ss.
COUNTY OF)

Michael R. Afremov, being duly sworn on oath, deposes and states:

1. I am a citizen of the United States and a resident of the State of Minnesota.

2. I am familiar with the septal occluding products produced by AGA Medical Corporation.

3. I am familiar with various properties of wire made from NiTi including "shape memory" properties and "superelastic" properties.

4. "Shape memory" properties are distinct properties from "superelastic" properties.

5. A wire made from NiTi may not have temperature responsive properties for a range of temperatures similar to the normal range of temperatures of the human body.

6. The septal occluding products produced by AGA Medical Corporation do not change shape or otherwise "respond" when exposed to the normal temperatures of the human body.

7. On or about May 25, 1999, I subjected a septal occluding device produced by AGA Medical Corporation to temperatures ranging from approximately 212°F to 49°F. There was no visible change in the shape or configuration of the device.

8. On or about May 25, 1999 I videotaped a septal occluding device produced by AGA Medical Corporation being placed in a beaker of boiling water by David E. Bakken. The device was kept in the boiling water for several minutes and there was no visible change in the shape or configuration of the device. The device was also placed in the beaker of water as the temperature of the water was varied from approximately 212°F to 49°F. There was no visible change in the shape or configuration of the device over these range of temperatures (see videotape attached to this exhibit).

9. The septal occluding products produced by AGA Medical Corporation do not include wires that are activated at body temperature.

Further affiant sayeth not.

Michael R. Afremov

STATE OF MINNESOTA)
) SS
COUNTY OF RICE)

On this 2nd day of June, 1999 before me, a Notary Public, for and within the aforesaid county, personally appeared Michael R. Afremov, to me known to be the person described in and who executed the foregoing instrument and acknowledged to me that he executed the same as his free act and deed.

(SEAL)

Notary Public

JODI L. LOCHER
NOTARY PUBLIC - MINNESOTA
MY COMMISSION EXPIRES
JANUARY 31, 2000

AGA 0000002

EXHIBIT R

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Boston, MA


Dr. Carrozza, MD

PHYSICIAN
Joseph Carrozza, MD

Beth Israel Deaconess Medical Center
Boston
MA
02215
(617) 632-7455
Certifications: ASD PFO
jcarrozz@caregroup.harvard.edu


Dr. Laham, MD

PHYSICIAN
Roger Laham, MD

Beth Israel Deaconess Medical Center
Boston
MA
02215
(617) 667-4138
Certifications: PFO
rlaham@bidmc.harvard.edu


Dr. Eisenhauer, MD

PHYSICIAN
Andrew C. Eisenhauer, MD

Brigham and Women's Hospital
Boston
MA
02115
(617) 732-8898
Certifications: ASD PDA
aeisenhauer@partners.org


Dr. Landzberg, MD

PHYSICIAN
Michael Landzberg, MD

Brigham and Women's Hospital
Boston
MA
02115
(617) 355-6508
Certifications: ASD PDA
michael.landzberg@cardio.chboston.org

PHYSICIAN
Alan Nugent, MD

Children's Hospital of Boston
Boston
MA
02115
(617) 355-3449
Certifications: ASD
alan.nugent@cardio.chboston.org

PHYSICIAN
Audrey Marshall, MD

Children's Hospital of Boston
Boston
MA
02115
(617) 355-8749
Certifications: ASD
audrey.marshall@tch.harvard.edu

PHYSICIAN
James E. Lock, MD

Children's Hospital of Boston
Boston
MA
02115
(617) 355-7313
Certifications: ASD PDA
james.lock@cardio.chboston.org


Dr. Landzberg, MD

PHYSICIAN
Michael Landzberg, MD

Children's Hospital of Boston
Boston
MA
02115
(617) 355-6508
Certifications: ASD PDA
michael.landzberg@cardio.chboston.org


Dr. Lang, MD

PHYSICIAN
Peter Lang, MD

Children's Hospital of Boston
Boston
MA
02115
(617) 355-8539
Certifications: ASD PDA
peter.lang@cardio.chboston.org


Dr. Inglessis, MD

PHYSICIAN
Ignacio Inglessis, MD

Massachusetts General Hospital
Boston
MA
02114
(617) 724-8052
Certifications: ASD PFO PDA
linglessis@partners.org


Dr. Palacios, MD

PHYSICIAN
Igor Palacios, MD

Massachusetts General Hospital
Boston
MA
02114
(617) 726-8424
Certifications: ASD PFO PDA
ipalacios@partners.org

PHYSICIAN
Michael de Moor, MD, FACC

Massachusetts General Hospital
Boston
MA
02114
(617) 726-2925


Dr. de Moor, MD

Certifications: ASD PFO PDA
mdemoor@partners.org


Dr. Kimmelstiel, MD

PHYSICIAN
Carey Kimmelstiel, MD

New England Medical Center
Boston
MA
02111
(617) 636-5914
Certifications: ASD PFO PDA
ckimmelstiel@tufts-nemc.org


Dr. Balaguru, MD

PHYSICIAN
Duraisamy Balaguru, MD

New England Medical Center
Boston
MA
02111
(617) 636-7435
Certifications: ASD PFO PDA
dbalaguru@tufts-nemc.org

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Burlington, MA

PHYSICIAN
Thomas Piemonte, MD

Lahey Clinic
Burlington
MA
01805
(781) 744-8254
Certifications: ASD
thomas_c_piemonte@lahey.org

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